

**Design Specification**

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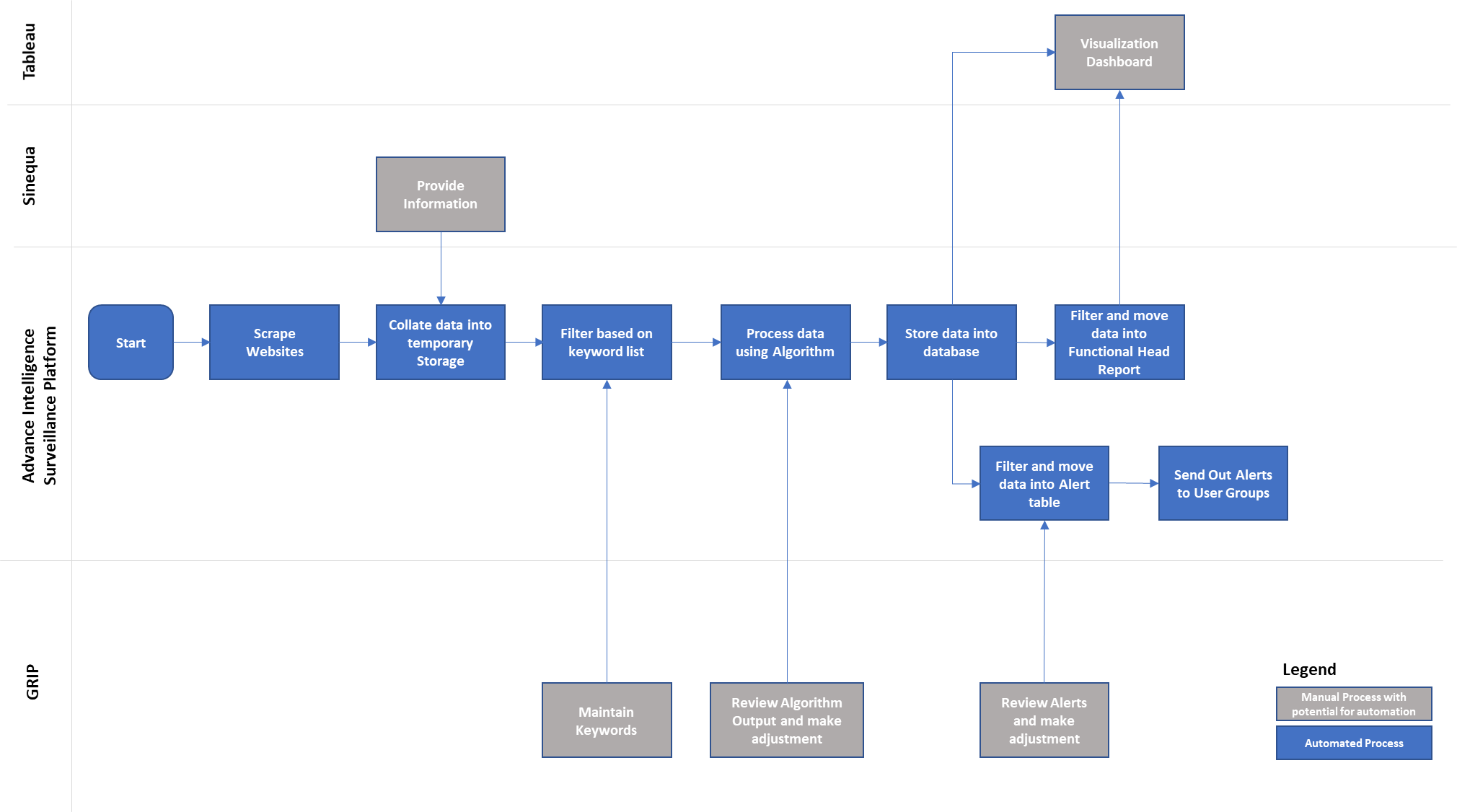
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# 1. Introduction/Purpose

This program is a proof of concept to develop data science capabilities to enable intelligence surveillance model with proactive information strategy. This platform would serve as a foundation to enable reuse of data science program capabilities across Astellas to meet broader use cases. It would enable Astellas adopt an automated method of monitoring and analyzing multiple sources of intelligence information across various regions and enable the dissemination of information that can potentially influence future programs for an accelerated drug launch. The key technology focus areas to achieve aforesaid objectives include text summarization approach with Natural Language Processing techniques, web scrapping and interactive visualizations.

# 2. Overview

This program includes a job that runs daily and crawls multiple web-based sources provided by business and then scrapes relevant data after passing through set checkpoints. The data is then passed through a transformation module, which transforms the data into suitable format for NLP Algorithms. Further, NLP Algorithm creates long and short summaries of all the entries. Finally, the ingestion modules are triggered to ingest data into a relational database which in turn is used for visualization purposes.



import requests

from bs4 import BeautifulSoup

import urllib3

from requests.adapters import HTTPAdapter

from urllib3.util import Retry

# Keywords that we need to match in th title

keywords = ['medical devices', 'implantable', 'software as medical device',

'samd', 'mdufa', 'harmonised standards',

'medical device coordination group (mdcg)',

'combination product', 'guidance', 'notified body',

'artificial intelligence medical devices',

'artificial intelligence/machine learning-enabled medical devices',

'machine learning-enabled medical devices',

'artificial intelligence medical devices',

'classification',

'designation', 'approval', 'recall', 'companion diagnostic',

'in vitro diagnostic (ivd)',

'device', 'software', 'health application', 'digital health',

'medical device regulation (mdr)', 'instruction for use (ifu)',

'medtech', 'unique device identification (udi)', '510(k)',

'investigational device exemption (ide)', 'de novo', 'premarket approval application (pma)',

'humanitarian device exemption (hde) ', 'device classification', 'iso', 'advamed', 'standard',

'eudamed', 'ce mark', 'declaration of conformity',

'general safety and performance requirements (gspr) ', 'european medicines agancy (ema)',

'european commission (ec)', 'eu reference laboratories (eurls)', 'eu expert panel',

'center for devices and radiological health (cdrh)', 'drug-device combination',

'national medical products administration (nmpa)',

'center for medical device evaluation (cmde)',

'medical device material', 'policy', 'swiss medtech']

'''

This is a utility function for formating the date

The format of date is : dd-mm-yyyy

return date in above format.

'''

def date\_format(str1):

'''

l[0] = Month

l[1] = Date

l[2] = Year

'''

str1 = str1.lower()

l1 = str1.replace(',','').split(' ')

# December -> dec

if (len(l1[0]) > 3):

l1[0] = l1[0][:3]

dict1 = {'jan' : '01',

'feb':'02',

'mar':'03',

'apr':'04',

'may':'05',

'jun':'06',

'jul':'07',

'aug':'08',

'sep':'09',

'oct':'10',

'nov':'11',

'dec':'12'

}

a = str(dict1[l1[0]])

return str(l1[1].zfill(2)+'-'+ a +'-'+str(l1[2]))

'''

This is a utilty function for checking keywords in title.

This function returns a list of matched keywords, if any.

Else it will retuern an empty list.

'''

def check\_keywords\_in\_title(title, keywords):

match = []

for word in keywords:

if word in title:

# print(word, "matched for title :", title)

match.append(word)

return match

'''

Beautifulsoup for getting the page

'''

def getPage(url):

try:

session = requests.Session()

retry = Retry(connect=3, backoff\_factor=0.5)

adapter = HTTPAdapter(max\_retries=retry)

session.mount('http://', adapter)

session.mount('https://', adapter)

req = session.get(url)

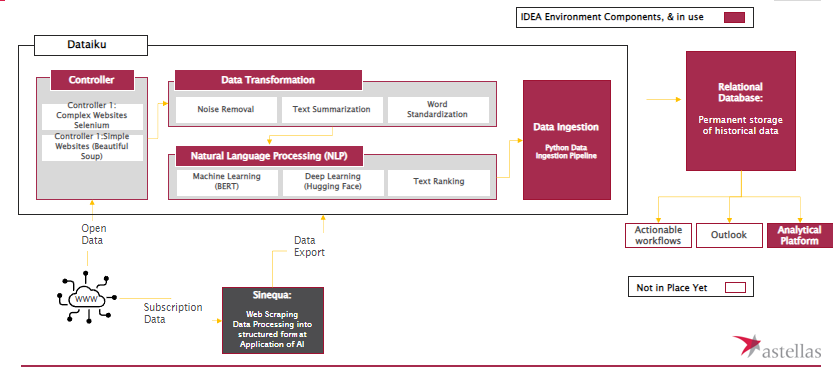
except requests.exceptions.RequestException:

return None

return BeautifulSoup(req.text, 'html.parser')

# 3. Component Explanation

Figure below shows the technical architecture



There are 5 components in this architecture i.e.

1. Controller
2. Data Transformation
3. NLP
4. Data Ingestion/ MS SQL Relational Database.
5. Dashboard / Visualization

## 3.1 Controller

This module collects data and content from a list of websites (Please find the list of websites at the end of this part). The data is initially kept locally for manipulation and analysis as and when needed. Based on the type of websites, we have created two controllers. The first controller deals with simple websites where JavaScript is not needed to load the content of websites. For such websites “Beautiful Soup” framework is used.

Beautiful Soup is a Python package used for parsing HTML and XML documents. It creates a parse tree for parsed pages that can be used to extract data from HTML, which is useful for web scraping.

On the other hand, modern web is becoming increasingly complex and reliant on JavaScript, making web-scraping often difficult even for small tasks. Usually, web scrapers in python do not execute java script and related web browser workflows, thus making some targets difficult to reach. In other words, the content is visible in the web-browser, but the scraper can't see it. For this, browser automation is frequently used in web-scraping to utilize browser rendering power to access all of the content. Selenium is a general web browser automation tool used in general task automation and web-scraping.

The controller collects the following data from each website:

1. Identifier
2. Title
3. Date (dd-mm-YYYY)
4. URL
5. Keyword(s) (“|” delimited)
6. Content

List of websites(s) covered in this POC are:

* '<https://www.ema.europa.eu>' - Container 1
* '<https://www.mddionline.com/regulatory-quality/regulations>' - Container 1
* '<https://www.fdanews.com/articles/topic/106?page=5>' - Container 1
* '<https://www.medtechdive.com/topic/medical-devices/>' - Container 1
* '<https://www.raps.org/news-and-articles/news-articles>' - Container 1
* '"<https://chinameddevice.com/cmd-blogs>"'
* '<https://www.pacificbridgemedical.com/resource-center/?cat_resource_type%5B%5D=17&cat_resource_market=0&_type=>' - Container 2

## 3.2 Data Transformation

Data transformation module converts data from one format or structure into another format or structure. It is a fundamental aspect for NLP Algorithm. The process follows linear steps as described in data transformation module I.e.

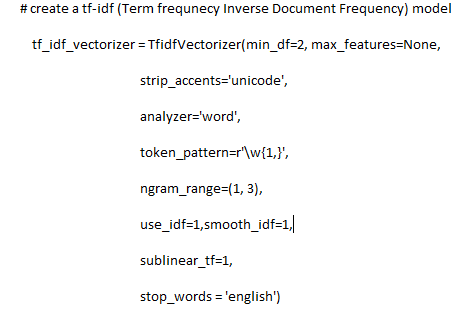
1. Noise Removal and Tokenization
2. Word Standardization

### 3.2.1 Noise Removal

Noise removal is the removal of punctuation, HTML tags, upper case, and generally anything that makes the text more than a series of words. Furthermore, when we have a collection of words, it’s time to add structure. Normally, this means creating a list of words with tokenization. Around this point, we remove the stop words from the partially processed text. Stop words is the term for words that exist for the sake of grammar, but don’t impart meaning once the sentence is gone.

### 3.2.2 Word Standardization

Text normalization is the process of transforming text into a single canonical form that it might not have had before. Normalizing text before storing or processing allows for separation of concerns, since input is guaranteed to be consistent before operations are performed on it.



## 3.3 Natural Language Processing (NLP)

In this module, we try to perform automatic summarization of processed content by shortening the data computationally, creating a subset that represents the most relevant and important information within the original text content. The text summarization is widely categorized into two types I.e.

1. Extraction-based summarization: As the name suggests, this technique relies on merely extracting or pulling out key phrases from a document. It is then followed by combining these key phrases to form a coherent summary.
2. Abstract-based summarization: This technique, unlike extraction, relies on being able to paraphrase and shorten parts of a document. When such abstraction is done correctly in deep learning problems, one can be sure to have consistent grammar. But this added layer of complexity comes at the cost of being harder to develop than extraction.

Considering the time constraints on the POC, we presented the business with two initial algorithms outputs

1. Text Ranking Algorithm – Extractive Model: TextRank is a graph-based algorithm for Natural Language Processing that can be used for keyword and sentence extraction. The algorithm is inspired by PageRank which was used by Google to rank websites.
2. HuggingFace Pre Trained model – Abstractive Model

And they liked the extraction-based model better, hence in the following iteration we tried the SoTA( State of The Art) BERT (Bidirectional Encoder Representations from Transformers is a transformer-based machine learning technique for natural language processing pre-training developed by Google.) pre trained model for text summarization.

BERT (Bidirectional transformer) is a transformer used to overcome the limitations of RNN and other neural networks as long-term dependencies. It is a pre-trained model that is naturally bidirectional. It uses a powerful flat architecture with inter sentence transform layers so as to get the best results in summarization and hence is the most efficient summarizer till date. In our module we are taking subsets as whole sentences, but it could be modified as per requirement to word chunks. Different number of sentences is used to derive Long and Short summaries.

## 3.4 Data Ingestion/ MS SQL Relational Database

We pass the data from NLP module through a data ingestion pipeline that make the necessary transformation like changing the date format to Italian, which is default for MS SQL Servers. The data is stored in tables with the following columns:

* Identifier
* Title
* Date (ddmmYYYY)
* URL
* Keyword(s) (“|” delimited)
* Long Summary
* Short Summary

The data is loaded in tables in an incremental fashion. All the new records are inserted and any changes in existing records are updated. We are using basic DML (Data Manipulation Language) for the manipulation of records in our table. This allows us to select/read data with some criteria or not, we can insert new data or edit existing ones. And, of course we can delete the records if we don’t need them anymore.

Database Structure

* Server Name - icdaue01db010.aic.astellas.net
* Database - ICDAUE01DW010
* Schema Name - ais\_poc
* Table Name for Article Details - Article\_Details

|  |  |
| --- | --- |
| **Column Name** | Data Type |
| Identifier | Varchar(2048) |
| Title | Varchar(2048) |
| Article\_URL | Varchar(2048) |
| Article\_Published\_Date | Date |
| Keywords | Varchar(2048) |
| Long\_Summary | Nvarchar(Max) |
| Short\_Summary | Nvarchar(Max) |

* Table Name for Website Details - Source\_Website\_Details

|  |  |
| --- | --- |
| **Column Name** | Data Type |
| Website\_URL | Varchar(2048) |
| Regulatory\_Agency | Varchar(2048) |
| Country | Varchar(2048) |

# 4. Feature Explanation

Advanced Intelligence Surveillance program will enable better use of the collective resources, technologies and platforms to drive real values. It will save a significant amount of time and money keeping Astellas up to date with the latest news. The job runs daily and hence the velocity, veracity and variety of data is better. The development team has also leveraged the flexibility of running the servers on Azure synapse which would make it easy to scale and simplify database management. It will boost availability, performance, management and programmability.

# Appendix

* + - 1. ais\_utilities

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session.mount('https://', adapter)

req = session.get(url)

except requests.exceptions.RequestException:

return None

return BeautifulSoup(req.text, 'html.parser')

* + - 1. IntegrationV2 – Container 1

import requests

from bs4 import BeautifulSoup

import re

import csv

import time

import urllib3

from datetime import date

import datetime

from ais\_utilities import date\_format

from ais\_utilities import check\_keywords\_in\_title

from ais\_utilities import keywords

from ais\_utilities import getPage

import html2text

"""

Data that needs to be captured are:

1. Identifier

2. Title - of the article

3. URL of the article

4. Date on which the article was published

5. Content of the article:- if there is a keyword match in the title.

All this data is stored in a dictionary as key-value pair

And all the dictionary is stores in a list.

This list is the return type of all the function(s) in this package

"""

# https://www.mddionline.com/regulatory-quality/regulations

def scrape\_mddionline(url):

cookie\_jar=requests.cookies.RequestsCookieJar()

session=requests.Session()

header = {'Accept-Encoding': 'gzip, deflate', 'Accept': '/', 'Connection': 'keep-alive',

"User-Agent":"Mozilla/5.0 (Windows NT 6.1; WOW64; rv:32.0) Gecko/20100101 Firefox/32.0"

}

all\_news=[]

try:

print("Utility function for https://www.mddionline.com/regulatory-quality/regulations called !")

bs = getPage(url)

table = bs.find\_all('article', attrs={'class':'article-teaser article-teaser\_\_icon\_\_article article-teaser\_\_aside'})

for row in table:

title = row.find('a').text.lower()

url\_content = row.find('a')['href']

date = date\_format(row.find('span').text.lstrip().rstrip())

news = {}

ret = check\_keywords\_in\_title(title, keywords)

print(title, "- Keywords matched are:- ", ret)

if ret:

match = ""

match = " | ".join(word for word in ret)

print(match)

news['keywords'] = match

url\_inner = 'https://www.mddionline.com' + url\_content

bs\_inner = getPage(url\_inner)

content\_inner = bs\_inner.find('div', {'itemprop':'articleBody'})

news['identifier'], news['title'], news['url'], news['date'], news['keywords'], news['content'] = url, title, url\_inner, date, match, ''

news['content'] = content\_inner.text.lstrip()

print("\t News content should be populated !")

all\_news.append(news)

else:

print("\t No Key Match, news content should not be populated !")

except:

print("An exception occured with:- ", url)

return all\_news

# https://www.ema.europa.eu

def scrapeEuropa(url):

cookie\_jar=requests.cookies.RequestsCookieJar()

session=requests.Session()

header = {'Accept-Encoding': 'gzip, deflate', 'Accept': '/', 'Connection': 'keep-alive',

"User-Agent":"Mozilla/5.0 (Windows NT 6.1; WOW64; rv:32.0) Gecko/20100101 Firefox/32.0"

}

all\_news=[]

try:

print("Utility function for https://www.ema.europa.eu called !")

bs = getPage(url)

table = bs.find('div', attrs = {'class':'view-content'})

for row in table.findAll('a', attrs = {'class':'ecl-link ecl-list-item\_\_link'}):

news = {}

news['identifier'] = url

news['title'] = row.h3.text

news['url']=row['href']

news['date'] = row.span.text.replace("/","-")

news['keywords'] = ''

title, url\_content, date, content = news['title'].lower(), news['url'], row.span.text ,''

ret = check\_keywords\_in\_title(title, keywords)

print(title, "- Keywords matched are:- ", ret)

if ret:

match = ""

match = " | ".join(word for word in ret)

print(match)

news['keywords'] = match

url\_inner = url + url\_content

bs\_inner = getPage(url\_inner)

table\_inner = bs\_inner.find('div', attrs = {'class':'paragraphs-items paragraphs-items-field-ema-paragraph-content paragraphs-items-field-ema-paragraph-content-full paragraphs-items-full'})

table\_inner\_1 = table\_inner.find('div', attrs = {'class':'ecl-field\_\_body'})

table\_inner\_2 = table\_inner\_1.findAll('p')

for i in table\_inner\_2:

content += i.get\_text()

news['content'] = content.replace("\n", " ")

print("\t News content should be populated !")

all\_news.append(news)

else:

print("\t No Key Match, news content should not be populated !")

except:

print("An exception occured with:- ", url)

return all\_news

# https://www.fdanews.com/articles/topic/106?page=5

def scrapeFDA(url):

all\_news=[]

try:

print("Utility function for https://www.fdanews.com called !")

bs = getPage(url)

# Checkpoint No. of records pulled is incorrect

table = bs.findAll('article', attrs = {'class':'record article-summary'})

for row in table:

news = {}

news['identifier'] = url

news['title'], news['url'] = row.h2.text, row.h2.a['href']

news['date'] = date\_format(row.find('div' , attrs = {'class' : 'date article-summary\_\_post-date'}).text)

title, url\_content, date, content = news['title'].lower(), news['url'], news['date'],''

ret = check\_keywords\_in\_title(title, keywords)

news['keywords'] = ''

print("check\_keywords\_in\_title called for title:- ", title)

if ret:

match = ""

match = " | ".join(word for word in ret)

print("\t Found a keyword!!")

news['keywords'] = match

url\_inner = url\_content

time.sleep(2)

bs\_inner = getPage(url\_inner)

table\_inner = bs\_inner.find('div', attrs = {'body gsd-paywall'})

table\_inner\_1 = table\_inner.findAll('p')

for i in table\_inner\_1:

content += i.get\_text()

news['content'] = content.replace("\n", " ")

all\_news.append(news)

print("\t News content should be populated !")

else:

print("\t No Key Match, news content should not be populated !")

time.sleep(2)

except:

print("An exception occured with:- ", url)

return all\_news

# https://www.medtechdive.com/topic/medical-devices/

def scrapeMedTechDive(url):

all\_news=[]

cookie\_jar=requests.cookies.RequestsCookieJar()

session=requests.Session()

header = {'Accept-Encoding': 'gzip, deflate', 'Accept': '/', 'Connection': 'keep-alive',

"User-Agent":"Mozilla/5.0 (Windows NT 6.1; WOW64; rv:32.0) Gecko/20100101 Firefox/32.0"

}

try:

print("Utility function for https://www.medtechdive.com/topic/medical-devices/ called !")

bs = getPage(url)

all\_news=[]

table = bs.find('ul', attrs = {'class':'feed layout-stack-xxl'})

for row in table.findAll('div', attrs = {'class':'medium-8 columns'}):

news = {}

news['identifier'] = url

if row.find("div", attrs = {"class":"label label--loud"}):

print("Loud Label Found... - ", url)

continue

news['title'] = row.h3.text.lstrip().rstrip()

news['url']=row.a['href']

dummy = row.findAll('span', attrs ={'class':'secondary-label'})[-1]

dummy = dummy.text.lstrip().rstrip().replace(",", "")

if 'Updated' in dummy or 'ago' in dummy:

today = datetime.date.today()

dummy = today.strftime("%B %d, %Y")

date = dummy.split(" ")[-3:]

date = ' '.join(date)

news['date'] = date\_format(date)

news['keywords'] = ''

title, url\_content, date, content = news['title'].lower(), news['url'], news['date'] ,''

ret = check\_keywords\_in\_title(title, keywords)

print(title, "- Keywords matched are:- ", ret)

if ret:

match = " "

match = " | ".join(word for word in ret)

print(match)

news['keywords'] = match

#print("\t Found a keyword!!")

base\_url = "https://www.medtechdive.com"

url\_inner = base\_url + url\_content

news['url'] = url\_inner

time.sleep(4)

bs\_inner = getPage(url\_inner)

table\_inner = bs\_inner.find('div', attrs = {'class':'large medium article-body'})

table\_inner\_1 = table\_inner.findAll('p')

for i in table\_inner\_1:

content += i.get\_text()

news['content'] = content.replace("\n", " ")

all\_news.append(news)

print("\t News content should be populated !")

else:

print("\t No Key Match, news content should not be populated !")

time.sleep(2)

except:

print("An exception occured with:- ", url)

return all\_news

# https://www.raps.org/news-and-articles/news-articles

def scrapeRaps(url):

all\_news = []

cookie\_jar=requests.cookies.RequestsCookieJar()

session=requests.Session()

header = {'Accept-Encoding': 'gzip, deflate', 'Accept': '/', 'Connection': 'keep-alive',

"User-Agent":"Mozilla/5.0 (Windows NT 6.1; WOW64; rv:32.0) Gecko/20100101 Firefox/32.0"

}

try:

print("Utility function for https://www.raps.org/news-and-articles/news-articles called !")

req = requests.get(url, headers = header)

soup=BeautifulSoup(req.content, "html.parser")

newsList = soup.findAll("div", {"class": "item-content"})

for eachNews in newsList:

news = {}

news['identifier'] = url

url\_content=eachNews.a['href']

title = eachNews.a.text.strip().lower()

date = eachNews.li.text

date1 = date.split(" ")

date = date1[1] + " " + date1[0] + " " + date1[2]

news['title'] = title

news['url'] = 'https://www.raps.org' + url\_content

news['date'] = date\_format(date)

news['keywords'] = ''

ret = check\_keywords\_in\_title(title, keywords)

print(title, "- Keywords matched are:- ", ret)

if ret:

match = ""

match = " | ".join(word for word in ret)

print(match)

news['keywords'] = match

print("\t Found a keyword!!")

req\_inner = requests.get(news['url'], headers = header)

soup\_inner = BeautifulSoup(req\_inner.content, "html.parser")

table = soup\_inner.find('div', attrs = {'class':'article'})

row = table.findAll('div')[1]

news['content'] = row.text

all\_news.append(news)

print("\t News content should be populated !")

else:

print("\t No Key Match, news content should not be populated !")

time.sleep(2)

except:

print("An exception occured with:- ", url)

return all\_news

# https://chinameddevice.com/cmd-blogs

def chinaMedDevice(url):

all\_news = []

cookie\_jar=requests.cookies.RequestsCookieJar()

session=requests.Session()

header = {'Accept-Encoding': 'gzip, deflate', 'Accept': '/', 'Connection': 'keep-alive',

"User-Agent":"Mozilla/5.0 (Windows NT 6.1; WOW64; rv:32.0) Gecko/20100101 Firefox/32.0"

}

try:

print("Utility function for https://chinameddevice.com/ called !")

soup = getPage(url)

articles = soup.find(attrs = {"class":

["elementor-posts-container",

"elementor-posts",

"elementor-posts--skin-classic",

"elementor-grid elementor-has-item-ratio"]})

table = articles.find\_all("article")

for article in table:

title = article.h3.text.lstrip().rstrip()

url\_content = article.a['href']

date1 = article.find("span", {"class":"elementor-post-date"}).text.lstrip().rstrip()

ret = check\_keywords\_in\_title(title.lower(), keywords)

print(title, "- Keywords matched are:- ", ret)

if ret:

news = {}

match = ""

match = " | ".join(word for word in ret)

print(match)

news['identifier'] = 'https://chinameddevice.com'

news['title'] = title

news['url'] = url\_content

news['date'] = date\_format(date1)

news['keywords'] = match

bs\_inner = getPage(news['url'])

content = ''

data = bs\_inner.select("div.elementor-element.elementor-element-3042338.elementor-widget.elementor-widget-theme-post-content")

h = html2text.HTML2Text()

h.body\_width = 0

h.ignore\_links = True

h.ignore\_images = True

for d in data:

content = content + d.text

news['content'] = content

all\_news.append(news)

else:

print("\t No Key Match, news content should not be populated !")

except:

print("Exception with:- ", url[5])

return all\_news

* + - 1. Container – 2

import requests

from bs4 import BeautifulSoup

import re

import csv

import time

import urllib3

from datetime import date

from ais\_utilities import date\_format

from ais\_utilities import check\_keywords\_in\_title

from ais\_utilities import keywords

from ais\_utilities import getPage

from selenium.webdriver import Chrome

from selenium.webdriver import ChromeOptions

from selenium.webdriver.chrome import options

from selenium.webdriver.common.by import By

from selenium.webdriver.support.ui import WebDriverWait

# -\*- coding: utf-8 -\*-

import dataiku

import pandas as pd, numpy as np

from dataiku import pandasutils as pdu

# Read recipe inputs

driver\_path = '/data/dss\_data/code-envs/python/ASTELLAS\_INTELLIGENT\_SURVEILLANCE\_AIS/lib64/python3.6/site-packages/chromedriver'

def getContent(url):

print("Getting content for:- ", url)

cookie\_jar=requests.cookies.RequestsCookieJar()

options = ChromeOptions()

driver = Chrome(executable\_path=driver\_path, options = options)

driver.implicitly\_wait(5)

wait = WebDriverWait(driver, 10)

driver.get(url)

table = driver.find\_elements\_by\_class\_name("xmsonormal")

for t in table:

print(t.text)

def pacific(url):

cookie\_jar=requests.cookies.RequestsCookieJar()

options = ChromeOptions()

options.add\_argument('--headless')

options.add\_argument('--disable-gpu')

driver = Chrome(executable\_path=driver\_path, options = options)

driver.implicitly\_wait(0.5)

driver.get('https://www.pacificbridgemedical.com/resource-center/?cat\_resource\_type%5B%5D=17&cat\_resource\_market=0&\_type=')

table = driver.find\_elements\_by\_tag\_name("article")

all\_news = []

for t in table:

news = {}

title = t.find\_element\_by\_class\_name("entry-title").text.lower()

url\_content = t.find\_element\_by\_tag\_name("a").get\_attribute('href')

date1 = date\_format(t.find\_element\_by\_tag\_name("time ").text)

ret = check\_keywords\_in\_title(title, keywords)

print("Checking for:- ", title)

if ret:

print("Keyword matched.........")

match = ""

match = " | ".join(word for word in ret)

print(match)

news['identifier'] = url

news['title'] = title

news['url'] = url\_content

news['date'] = date1

news['keywords'] = match

all\_news.append(news)

else:

print("\t No keywords matched.......")

for news in all\_news:

options = ChromeOptions()

options.add\_argument('--headless')

options.add\_argument('--disable-gpu')

driver = Chrome(executable\_path = driver\_path, options = options)

driver.implicitly\_wait(5)

wait = WebDriverWait(driver, 10)

driver.get(news['url'])

table = driver.find\_elements\_by\_class\_name("entry-content")

content = ''

print("Content pouplated............ for ",news['title'])

for t in table:

content += t.text

news['content'] = content

driver.close()

return all\_news

* + - 1. BERT Test Code

!pip install summarizer

!pip install bert-extractive-summarizer

In [0]:

**from** **summarizer** **import** Summarizer

body = 'Text body that you want to summarize with BERT'

body2 = 'Something else you want to summarize with BERT'

model = Summarizer()

model(body)

model(body2)

In [0]:

*'''*

*Specifying number of sentences*

*Number of sentences can be supplied as a ratio or an integer. Examples are provided below.*

*'''*

**from** **summarizer** **import** Summarizer

body = 'Text body that you want to summarize with BERT'

model = Summarizer()

result = model(body, ratio=0.2) *# Specified with ratio*

result = model(body, num\_sentences=3) *# Will return 3 sentences*

In [0]:

*'''*

*Using multiple hidden layers as the embedding output*

*You can also concat the summarizer embeddings for clustering. A simple example is below.*

*'''*

**from** **summarizer** **import** Summarizer

body = 'Text body that you want to summarize with BERT'

model = Summarizer('distilbert-base-uncased', hidden=[-1,-2], hidden\_concat=**True**)

result = model(body, num\_sentences=3)

In [0]:

!pip install transformers

In [0]:

**from** **summarizer** **import** Summarizer

body = '''

The Chrysler Building, the famous art deco New York skyscraper, will be sold for a small fraction of its previous sales price.

The deal, first reported by The Real Deal, was for $150 million, according to a source familiar with the deal.

Mubadala, an Abu Dhabi investment fund, purchased 90**% o**f the building for $800 million in 2008.

Real estate firm Tishman Speyer had owned the other 10%.

The buyer is RFR Holding, a New York real estate company.

Officials with Tishman and RFR did not immediately respond to a request for comments.

It's unclear when the deal will close.

The building sold fairly quickly after being publicly placed on the market only two months ago.

The sale was handled by CBRE Group.

The incentive to sell the building at such a huge loss was due to the soaring rent the owners pay to Cooper Union, a New York college, for the land under the building.

The rent is rising from $7.75 million last year to $32.5 million this year to $41 million in 2028.

Meantime, rents in the building itself are not rising nearly that fast.

While the building is an iconic landmark in the New York skyline, it is competing against newer office towers with large floor-to-ceiling windows and all the modern amenities.

Still the building is among the best known in the city, even to people who have never been to New York.

It is famous for its triangle-shaped, vaulted windows worked into the stylized crown, along with its distinctive eagle gargoyles near the top.

It has been featured prominently in many films, including Men in Black 3, Spider-Man, Armageddon, Two Weeks Notice and Independence Day.

The previous sale took place just before the 2008 financial meltdown led to a plunge in real estate prices.

Still there have been a number of high profile skyscrapers purchased for top dollar in recent years, including the Waldorf Astoria hotel, which Chinese firm Anbang Insurance purchased in 2016 for nearly $2 billion, and the Willis Tower in Chicago, which was formerly known as Sears Tower, once the world's tallest.

Blackstone Group (BX) bought it for $1.3 billion 2015.

The Chrysler Building was the headquarters of the American automaker until 1953, but it was named for and owned by Chrysler chief Walter Chrysler, not the company itself.

Walter Chrysler had set out to build the tallest building in the world, a competition at that time with another Manhattan skyscraper under construction at 40 Wall Street at the south end of Manhattan. He kept secret the plans for the spire that would grace the top of the building, building it inside the structure and out of view of the public until 40 Wall Street was complete.

Once the competitor could rise no higher, the spire of the Chrysler building was raised into view, giving it the title.

'''

model = Summarizer()

result = model(body, min\_length=60)

full = ''.join(result)

print(full)

Output:

loading configuration file https://huggingface.co/bert-large-uncased/resolve/main/config.json from cache at /root/.cache/huggingface/transformers/1cf090f220f9674b67b3434decfe4d40a6532d7849653eac435ff94d31a4904c.1d03e5e4fa2db2532c517b2cd98290d8444b237619bd3d2039850a6d5e86473d

Model config BertConfig {

"architectures": [

"BertForMaskedLM"

],

"attention\_probs\_dropout\_prob": 0.1,

"classifier\_dropout": null,

"gradient\_checkpointing": false,

"hidden\_act": "gelu",

"hidden\_dropout\_prob": 0.1,

"hidden\_size": 1024,

"initializer\_range": 0.02,

"intermediate\_size": 4096,

"layer\_norm\_eps": 1e-12,

"max\_position\_embeddings": 512,

"model\_type": "bert",

"num\_attention\_heads": 16,

"num\_hidden\_layers": 24,

"output\_hidden\_states": true,

"pad\_token\_id": 0,

"position\_embedding\_type": "absolute",

"transformers\_version": "4.17.0",

"type\_vocab\_size": 2,

"use\_cache": true,

"vocab\_size": 30522

}

loading weights file https://huggingface.co/bert-large-uncased/resolve/main/pytorch\_model.bin from cache at /root/.cache/huggingface/transformers/1d959166dd7e047e57ea1b2d9b7b9669938a7e90c5e37a03961ad9f15eaea17f.fea64cd906e3766b04c92397f9ad3ff45271749cbe49829a079dd84e34c1697d

Some weights of the model checkpoint at bert-large-uncased were not used when initializing BertModel: ['cls.predictions.decoder.weight', 'cls.predictions.transform.dense.bias', 'cls.predictions.bias', 'cls.predictions.transform.LayerNorm.weight', 'cls.predictions.transform.dense.weight', 'cls.seq\_relationship.weight', 'cls.predictions.transform.LayerNorm.bias', 'cls.seq\_relationship.bias']

- This IS expected if you are initializing BertModel from the checkpoint of a model trained on another task or with another architecture (e.g. initializing a BertForSequenceClassification model from a BertForPreTraining model).

- This IS NOT expected if you are initializing BertModel from the checkpoint of a model that you expect to be exactly identical (initializing a BertForSequenceClassification model from a BertForSequenceClassification model).

All the weights of BertModel were initialized from the model checkpoint at bert-large-uncased.

If your task is similar to the task the model of the checkpoint was trained on, you can already use BertModel for predictions without further training.

loading file https://huggingface.co/bert-large-uncased/resolve/main/vocab.txt from cache at /root/.cache/huggingface/transformers/e12f02d630da91a0982ce6db1ad595231d155a2b725ab106971898276d842ecc.d789d64ebfe299b0e416afc4a169632f903f693095b4629a7ea271d5a0cf2c99

loading file https://huggingface.co/bert-large-uncased/resolve/main/added\_tokens.json from cache at None

loading file https://huggingface.co/bert-large-uncased/resolve/main/special\_tokens\_map.json from cache at None

loading file https://huggingface.co/bert-large-uncased/resolve/main/tokenizer\_config.json from cache at /root/.cache/huggingface/transformers/300ecd79785b4602752c0085f8a89c3f0232ef367eda291c79a5600f3778b677.20430bd8e10ef77a7d2977accefe796051e01bc2fc4aa146bc862997a1a15e79

loading configuration file https://huggingface.co/bert-large-uncased/resolve/main/config.json from cache at /root/.cache/huggingface/transformers/1cf090f220f9674b67b3434decfe4d40a6532d7849653eac435ff94d31a4904c.1d03e5e4fa2db2532c517b2cd98290d8444b237619bd3d2039850a6d5e86473d

Model config BertConfig {

"\_name\_or\_path": "bert-large-uncased",

"architectures": [

"BertForMaskedLM"

],

"attention\_probs\_dropout\_prob": 0.1,

"classifier\_dropout": null,

"gradient\_checkpointing": false,

"hidden\_act": "gelu",

"hidden\_dropout\_prob": 0.1,

"hidden\_size": 1024,

"initializer\_range": 0.02,

"intermediate\_size": 4096,

"layer\_norm\_eps": 1e-12,

"max\_position\_embeddings": 512,

"model\_type": "bert",

"num\_attention\_heads": 16,

"num\_hidden\_layers": 24,

"pad\_token\_id": 0,

"position\_embedding\_type": "absolute",

"transformers\_version": "4.17.0",

"type\_vocab\_size": 2,

"use\_cache": true,

"vocab\_size": 30522

}

The Chrysler Building, the famous art deco New York skyscraper, will be sold for a small fraction of its previous sales price. The deal, first reported by The Real Deal, was for $150 million, according to a source familiar with the deal. The building sold fairly quickly after being publicly placed on the market only two months ago. The incentive to sell the building at such a huge loss was due to the soaring rent the owners pay to Cooper Union, a New York college, for the land under the building.

"\nThe Chrysler Building, the famous art deco New York skyscraper, will be sold for a small fraction of its previous sales price. \nThe building sold fairly quickly after being publicly placed on the market only two months ago.\nThe incentive to sell the building at such a huge loss was due to the soaring rent the owners pay to Cooper Union, a New York college, for the land under the building.'\nStill the building is among the best known in the city, even to people who have never been to New York.\n"

* + - 1. Main Script

import requests

from bs4 import BeautifulSoup

import re

import csv

import time

import urllib3

from datetime import date

from datetime import date

from ais\_utilities import date\_format

from ais\_utilities import check\_keywords\_in\_title

from ais\_utilities import keywords

from ais\_utilities import getPage

# from pacific import getContent, pacific

from IntegrationV2 import scrapeEuropa, scrape\_mddionline, scrapeFDA, scrapeMedTechDive, scrapeRaps

from IntegrationV2 import chinaMedDevice

dataHuggingFace = []

'''

Conatiner 1 : Websites that could be scraped without selenium: i.e. we do not need to render

javascript on browser for the websites to to produce data

Container 2 : We need to render the code on Javascript in a browser to get the data

'https://www.ema.europa.eu' - Container 1

'https://www.mddionline.com/regulatory-quality/regulations' - Container 1

'https://www.fdanews.com/articles/topic/106?page=5' - Container 1

'https://www.medtechdive.com/topic/medical-devices/' - Container 1

'https://www.raps.org/news-and-articles/news-articles' - Container 1

'"https://chinameddevice.com/cmd-blogs"'

'https://www.pacificbridgemedical.com/resource-center/?cat\_resource\_type%5B%5D=17&cat\_resource\_market=0&\_type=' - Container 2

'''

url = ['https://www.ema.europa.eu',

'https://www.mddionline.com/regulatory-quality/regulations',

'https://www.fdanews.com/articles/topic/106?page=5',

'https://www.medtechdive.com/topic/medical-devices/',

'https://www.raps.org/news-and-articles/news-articles',

'https://www.pacificbridgemedical.com/resource-center/?cat\_resource\_type%5B%5D=17&cat\_resource\_market=0&\_type=',

"https://chinameddevice.com/cmd-blogs"

]

#Calling 'https://www.pacificbridgemedical.com/resource-center/?cat\_resource\_type%5B%5D=17&cat\_resource\_market=0&\_type=' website's function

'''

all\_news = pacific(url[5])

if len(all\_news) > 1:

print("Data for:-", url[5], " populated successfully !!")

dataHuggingFace.append(all\_news)

'''

time.sleep(3)

# Calling 'https://www.ema.europa.eu' website's function

all\_news = scrapeEuropa(url[0])

if len(all\_news) > 1:

print("Data for:-", url[0], " populated successfully !!")

dataHuggingFace.append(all\_news)

time.sleep(2)

# Calling 'https://www.mddionline.com/regulatory-quality/regulations' website's function

all\_news = scrape\_mddionline(url[1])

if len(all\_news) > 1:

print("Data for:-", url[1], " populated successfully !!")

dataHuggingFace.append(all\_news)

time.sleep(2)

# Calling 'https://www.fdanews.com/articles/topic/106?page=5' website's function

all\_news = scrapeFDA(url[2])

if len(all\_news) > 1:

print("Data for:-", url[2], " populated successfully !!")

dataHuggingFace.append(all\_news)

time.sleep(2)

# Calling 'https://www.medtechdive.com/topic/medical-devices/' website's function

all\_news = scrapeMedTechDive(url[3])

if len(all\_news) > 1:

print("Data for:-", url[3], " populated successfully !!")

dataHuggingFace.append(all\_news)

time.sleep(2)

# Calling 'https://www.raps.org/news-and-articles/news-articles' website's function

all\_news = scrapeRaps(url[4])

if len(all\_news) > 1:

print("Data for:-", url[4], " populated successfully !!")

dataHuggingFace.append(all\_news)

time.sleep(2)

# Calling 'https://chinameddevice.com/cmd-blogs' website's function

#all\_news = chinaMedDevice(url[6])

'''

if len(all\_news) > 1:

print("Data for:-", url[6], " populated successfully !!")

dataHuggingFace.append(all\_news)

print("Data Population in list of dictionaries")

'''

* + - 1. BERT Main Script:

In [1]:

import MainScript

Utility function for https://www.ema.europa.eu called !

ema establishes cancer medicines forum with academia to optimise cancer treatments in clinical practice - Keywords matched are:- []

No Key Match, news content should not be populated !

advice to sponsors on managing the impact of the war in ukraine on clinical trials - Keywords matched are:- []

No Key Match, news content should not be populated !

ema starts rolling review of covid-19 vaccine hipra (phh-1v) - Keywords matched are:- []

No Key Match, news content should not be populated !

new gene therapy to treat adult patients with multiple myeloma - Keywords matched are:- []

No Key Match, news content should not be populated !

meeting highlights from the committee for medicinal products for human use (chmp) 21-24 march 2022 - Keywords matched are:- []

No Key Match, news content should not be populated !

ema recommends authorisation of covid-19 medicine evusheld - Keywords matched are:- []

No Key Match, news content should not be populated !

Utility function for https://www.mddionline.com/regulatory-quality/regulations called !

vivosense exits stealth mode with a big series a round - Keywords matched are:- []

No Key Match, news content should not be populated !

poland gets its first robotic electrophysiology program - Keywords matched are:- []

No Key Match, news content should not be populated !

tactics for developing connected medical devices - Keywords matched are:- ['medical devices', 'device']

medical devices | device

News content should be populated !

some diagnostics companies can breathe a sigh of relief - Keywords matched are:- []

No Key Match, news content should not be populated !

cloudcath wins fda nod for connected device that brings dialysis to the home - Keywords matched are:- ['device']

device

News content should be populated !

novel wound care systems shipped to ukraine - Keywords matched are:- []

No Key Match, news content should not be populated !

abbott's new collaboration looks at diversity & equity gaps - Keywords matched are:- []

No Key Match, news content should not be populated !

lessons from the evolution of the automated external defibrillator - Keywords matched are:- []

No Key Match, news content should not be populated !

Data for:- https://www.mddionline.com/regulatory-quality/regulations populated successfully !!

Utility function for https://www.fdanews.com called !

check\_keywords\_in\_title called for title:- neogenomics presents clinical data for its radar lung cancer assay

No Key Match, news content should not be populated !

check\_keywords\_in\_title called for title:- orthofix receives fda’s 510(k) clearance for its truelok evo ring fixation system

Found a keyword!!

News content should be populated !

check\_keywords\_in\_title called for title:- advamed says covid-19 test manufacturing must be beefed up

Found a keyword!!

News content should be populated !

check\_keywords\_in\_title called for title:- biomérieux gets fda’s 510(k) clearance for its mass spectrometry system

Found a keyword!!

News content should be populated !

check\_keywords\_in\_title called for title:- enteral device industry phasing out ‘legacy’ enteral connectors

Found a keyword!!

News content should be populated !

check\_keywords\_in\_title called for title:- ufp buys advant medical, expanding catheter and guidewire lines

No Key Match, news content should not be populated !

check\_keywords\_in\_title called for title:- fda authorizes two siemens covid-19 tests

No Key Match, news content should not be populated !

check\_keywords\_in\_title called for title:- fda provides update on celltrion’s recall of some lots of its covid-19 test

Found a keyword!!

News content should be populated !

Data for:- https://www.fdanews.com/articles/topic/106?page=5 populated successfully !!

Utility function for https://www.medtechdive.com/topic/medical-devices/ called !

notified body update dampens hopes of near-term surge in ivdr capacity - Keywords matched are:- ['notified body']

notified body

News content should be populated !

pear expects $22m in revenue this year, as it banks on growing adoption of digital therapeutics - Keywords matched are:- []

No Key Match, news content should not be populated !

fda asks congress for 14% bump in device budget for supply chain, cybersecurity programs - Keywords matched are:- ['device']

device

News content should be populated !

mdr updates safety, clinical performance requirement for high-risk devices - Keywords matched are:- ['device']

device

News content should be populated !

stryker, zimmer don't expect near-term titanium supply impact from russia-ukraine war - Keywords matched are:- []

No Key Match, news content should not be populated !

congressman asks fda for information on oversight of medtronic's troubled hvad - Keywords matched are:- []

No Key Match, news content should not be populated !

resmed ceo expects another tough quarter as supply chain woes continue - Keywords matched are:- []

No Key Match, news content should not be populated !

fda sets terms for mdufa v agreement - Keywords matched are:- ['mdufa']

mdufa

News content should be populated !

another philips ventilator recall gets class i label from the fda - Keywords matched are:- ['recall']

recall

News content should be populated !

fda labels philips 2018 field correction for ventilators a class i recall - Keywords matched are:- ['recall']

recall

News content should be populated !

dexcom's hospital glucose monitor leads latest fda breakthrough designations - Keywords matched are:- ['designation']

designation

News content should be populated !

'on high alert': hospitals wary of cyber threats from russia-ukraine war - Keywords matched are:- []

No Key Match, news content should not be populated !

us appeals court rules in favor of nevro in patent dispute with boston scientific - Keywords matched are:- []

No Key Match, news content should not be populated !

'not for the faint of heart': insulet ceo talks tandem and medtronic competition, omnipod 5 launch - Keywords matched are:- []

No Key Match, news content should not be populated !

french, german medtech groups call for at least 2-year extension of mdr's transition period - Keywords matched are:- ['medtech']

medtech

News content should be populated !

fda identified 28 suppliers unaware of philips sleep device recall - Keywords matched are:- ['recall', 'device']

recall | device

News content should be populated !

us replaces eu as priority market for medtech industry: survey - Keywords matched are:- ['medtech']

medtech

News content should be populated !

steep drop in medical device reports on bayer's essure in 2021, fda data show - Keywords matched are:- ['device']

device

News content should be populated !

apyx's surgical device gets fda warning on off-label skin procedure use - Keywords matched are:- ['device']

device

News content should be populated !

zimvie ceo talks company spinoff, new technologies - Keywords matched are:- []

No Key Match, news content should not be populated !

ge healthcare profit forecasts meet estimates; spinoff details remain cloudy - Keywords matched are:- []

No Key Match, news content should not be populated !

fda orders philips to notify customers about sleep device recall due to 'inadequate' prior efforts - Keywords matched are:- ['recall', 'device']

recall | device

News content should be populated !

fda reaches mdufa v agreement with industry - Keywords matched are:- ['mdufa']

mdufa

News content should be populated !

fda warns of cyber vulnerabilities in medical device software components - Keywords matched are:- ['device', 'software']

device | software

News content should be populated !

medtronic, nevro boosted by expansion of medicare coverage for diabetic pain devices - Keywords matched are:- ['device']

device

News content should be populated !

Data for:- https://www.medtechdive.com/topic/medical-devices/ populated successfully !!

Utility function for https://www.raps.org/news-and-articles/news-articles called !

shuren apologizes for mdufa delay, says fda will start closing the spigot on new euas - Keywords matched are:- ['mdufa']

mdufa

Found a keyword!!

News content should be populated !

fda approvals roundup: pluvicto, cabenuva, fintepla - Keywords matched are:- ['approval']

approval

Found a keyword!!

News content should be populated !

eu regulators tell sponsors to apply covid flexibilities to trials impacted by ukraine war - Keywords matched are:- []

No Key Match, news content should not be populated !

white paper: rwd can support multi-cancer early detection screening test submissions - Keywords matched are:- []

No Key Match, news content should not be populated !

recon: fda approves antares’ oral testosterone drug; europe’s biotech industry face tough times, restructuring amid ‘dwindling’ cash - Keywords matched are:- []

No Key Match, news content should not be populated !

fda reprimands two firms for missing validation programs, poor facility maintenance - Keywords matched are:- []

No Key Match, news content should not be populated !

fda officials aim to stop misuse of the term ‘digital biomarker’ - Keywords matched are:- []

No Key Match, news content should not be populated !

fda authorizes second round of mrna boosters for older and immunocompromised people - Keywords matched are:- []

No Key Match, news content should not be populated !

recon: fda approves 2mg dose of novo’s diabetes drug ozempic; vaccine industry facing slowing demand, possible glut of covid-19 vaccines - Keywords matched are:- []

No Key Match, news content should not be populated !

asia-pacific roundup: philippine fda seeks feedback on expedited evaluation of medical devices - Keywords matched are:- ['medical devices', 'device']

medical devices | device

Found a keyword!!

News content should be populated !

fda seeks $8.4b in fy2023 to modernize regulatory infrastructure, prep for future pandemics - Keywords matched are:- []

No Key Match, news content should not be populated !

chmp recommends five new medicines, including gene therapy for multiple myeloma - Keywords matched are:- []

No Key Match, news content should not be populated !

Data for:- https://www.raps.org/news-and-articles/news-articles populated successfully !!

In [2]:

from MainScript import dataHuggingFace

from sklearn.feature\_extraction.text import TfidfVectorizer

from spacy.lang.en import English

import numpy as np

import pandas as pd

In [3]:

dataHuggingFace

Out[3]:

[[{'keywords': 'medical devices | device',

'identifier': 'https://www.mddionline.com/regulatory-quality/regulations',

'title': 'tactics for developing connected medical devices',

'url': 'https://www.mddionline.com/digital-health/tactics-developing-connected-medical-devices',

'date': '30-03-2022',

'content': 'Collaboration across medical device development teams is always a good idea, but it may be even more important with connected medical devices.\n“New technologies and shifting healthcare workflows are driving the pace of medtech devices faster than ever before,” Philip Remedios, principal, CFO, and director of design and development, BlackHӓgen Design, told MD+DI. “It is desirable to be an early provider of these new devices, so in order to reduce time-to-market, device companies need to move toward higher levels of concurrent collaboration among disparate development teams involved in traditional embedded design, application software, and other connected technologies.”\nSuch fast-paced medtech development “drives revised strategies for product definitions and new iterations to reduce scope, risk, and ultimately, time,” he explained.\nRemedios will explore the potential of such strategies in the MD&M West conference session, "Outsprint Your Competition to Market Launch by Streamlining Your Collaboration Roadmap," held in Room 210AB April 12 from 9:30 – 10:15 a.m.\n“Attendees will learn how to establish stakeholder strategy alignment early on with collaboration among executive, technical, marketing, manufacturing, sales, and service teams,” Remedios said. “Paralleling upfront tasks like product road-mapping and market access strategy, speed to first product launch can be dramatically accelerated. Considering best practices, attendees will also learn how to plan for rapid development cycles by frontloading iterative prototype development and usability testing to validate design specifications and direction.”\nRemedios will then moderate a panel discussion, Connected Device Design: Using Best Practices During the Product Development Process,\xa0shortly after in 208AB on April 12 from 10:30 – 11:15 a.m. He will be joined by panelists Tom Ulrich, Ph.D. and Chief Scientist, Tandem Diabetes Care; Jeff Gross, Chief Technology Officer, Canary Medical; and Patrick Bangert, Vice President of AI, Samsung, SDSA.\nThe group will discuss how to overcome the complexities of designing a connected medical device, including hardware and software design that incorporate robust cloud architecture, wireless protocols, machine learning, artificial intelligence, and cybersecurity.\n“The safety and efficacy of a connected device is driven by the design integrity across a network of adjacent products and processes in a wider ecosystem,” Remedios explained. Attendees of the panel discussion “will learn development best practices that maximize the stability of interoperative technologies and the regulatory landscape, including privacy and use-safety challenges associated with widely varying environmental and operating conditions.” Examples will be presented across screening/diagnostics, disease management, and digital therapeutics, he added.\n'},

{'keywords': 'device',

'identifier': 'https://www.mddionline.com/regulatory-quality/regulations',

'title': 'cloudcath wins fda nod for connected device that brings dialysis to the home',

'url': 'https://www.mddionline.com/digital-health/cloudcath-wins-fda-nod-connected-device-brings-dialysis-home',

'date': '30-03-2022',

'content': 'Patients with end-stage renal disease (ESRD) who are awaiting transplant are burdened with high-cost care and spending hours in a dialysis center to maintain some functionality in their kidneys. Approval for the CloudCath System may help some patients complete dialysis at home under the watchful eye of clinicians monitoring the device remotely, and at a significantly reduced cost. The company’s first-of-its-kind at-home peritoneal dialysis (PD) system won FDA 510(k) approval and is expected to have a limited launch in 2022, followed by full commercial launch in 2023.\nDialysis care can be extremely expensive, averaging about $89,000 annually while at-home care can offer a significant cost savings at about $53,000 annually, according to the National Kidney Foundation’s American Journal of Kidney Diseases. At-home continuous monitoring may also help to avoid exacerbations, according to Aly Elbadry, chief executive officer of CloudCath.\nDialysis Monitoring to Avoid Clinical Deterioration\n“The CloudCath device is designed to support the clinician/patient partnership for at-home PD therapy,” said Elbadry, adding, “Actually, the entire dialysis ecosystem has a current and urgent goal to maximize use of home modalities.” Additional monitoring steps are expected to avert health decline. With a cloud-based digital connection, the PD monitoring system continuously provides data that can tip a physician off to a brewing health issue.\n“Promising early data with the CloudCath System shows patients and clinicians may be alerted to the need for evaluation days before the onset of symptoms, enabling patients to seek early medical intervention, diagnosis, and treatment before escalation to hospitalization, catheter removal or death,” he said.\nIntegrates with Current CCPD System\nThe ongoing and nonobtrusive nature of the device allows it to be added to ESRD care with minimal effort on the part of the patient or his/her family. Patients can continue to use their current continuous cyclic PD (CCPD) device with CloudCath. The monitoring system is designed to integrate with a patient’s existing device, according to Elbadry. “Patients simply connect the CloudCath sensor and drain set, similar to their current drain set extensions, to their at-home CCPD cycler,” he said.\n“As the dialysate fluid is drained, the CloudCath sensor uses advanced digital, optical sensors to assess the turbidity of fluid,” Elbadry said. “Changes in fluid turbidity are detected by CloudCath’s proprietary cloud-based algorithm and notifications are sent to clinicians and patients to alert them to seek additional medical evaluation.”\nCloudCath’s system has the potential to shift the PD monitoring landscape which in its current state is fragmented, with options ranging from paper-based tests, evaluating drainage lines, or waiting for symptoms. Instead, CloudCath’s device system looks for signs of infection or complication indicated by clouded dialysate fluid. When cloudy fluid is detected by the PD monitoring system, it is a trigger for the patient and physician to coordinate additional care.\nNew Standard of Dialysis Care with Monitoring\nCloudCath envisions the monitoring system could be part of future standard of care in PD for ESRD patients. That could also extend to other settings. “Although focused on home PD, of\xa0course, the CloudCath System can also be used in healthcare settings like longterm care facilities and, in the rare case that a patient moves to a hospital and continues PD treatment, the CloudCath System could be used in a hospital setting,” said Elbadry.\n'}],

[{'identifier': 'https://www.fdanews.com/articles/topic/106?page=5',

'title': 'Orthofix Receives FDA’s 510(k) Clearance for its TrueLok EVO Ring Fixation System',

'url': 'https://www.fdanews.com/articles/207065-orthofix-receives-fdas-510k-clearance-for-its-truelok-evo-ring-fixation-system',

'date': '22-03-2022',

'keywords': '510(k)',

'content': 'Orthofix Medical has been granted the FDA’s 510(k) clearance for its TrueLok EVO ring fixation system (EVO is short for “evolution”).The external fixation device for the lower leg and foot is for use in complex limb reconstruction and deformity correction procedures, according to the Lewisville, Tex.-based company.The device, which features radiolucent rings and struts for clear radiographic visualization, is intended to let physicians better assess bone anatomy during surgery and postoperative care.TrueLok EVO is available as a preassembled frame in ready-to-use, single-use sterile packaging, which makes application easier, potentially saving time during surgery, the company said. '},

{'identifier': 'https://www.fdanews.com/articles/topic/106?page=5',

'title': 'AdvaMed Says COVID-19 Test Manufacturing Must Be Beefed Up',

'url': 'https://www.fdanews.com/articles/207064-advamed-says-covid-19-test-manufacturing-must-be-beefed-up',

'date': '22-03-2022',

'keywords': 'advamed',

'content': 'The device trade association AdvaMed has issued an urgent call for more federal funding to produce COVID-19 diagnostic tests because the administration announced that its efforts would have to be scaled back unless Congress appropriates more money.“Should we face another wave of cases, we must be prepared to meet the needs of patients and public health, and we cannot do that without firm public-private commitments in place with test manufacturers,” said AdvaMed President and CEO Scott Whitaker.Among other measures, the association wants the federal government to partner with the device industry for “warm base manufacturing” arrangements. \xa0A\xa0warm base\xa0refers to facilities that would be constructed and commissioned, ready to quickly\xa0manufacture products on demand. '},

{'identifier': 'https://www.fdanews.com/articles/topic/106?page=5',

'title': 'BioMérieux Gets FDA’s 510(k) Clearance for its Mass Spectrometry System',

'url': 'https://www.fdanews.com/articles/207063-biom%C3%A9rieux-gets-fdas-510k-clearance-for-its-mass-spectrometry-system',

'date': '22-03-2022',

'keywords': '510(k)',

'content': 'In vitro diagnostics company bioMérieux’s Vitek MS Prime mass spectrometry identification system has received 510(k) clearance from the FDA.The compact benchtop system is integrated with the company’s fully automated Vitek 2 system for bacterial identification and antibiotic susceptibility testing.\xa0The Vitek MS Prime system allows for prioritization of urgent samples and continuous “load and go” operation, the company said. '},

{'identifier': 'https://www.fdanews.com/articles/topic/106?page=5',

'title': 'Enteral Device Industry Phasing Out ‘Legacy’ Enteral Connectors',

'url': 'https://www.fdanews.com/articles/207044-enteral-device-industry-phasing-out-legacy-enteral-connectors',

'date': '21-03-2022',

'keywords': 'device',

'content': 'Manufacturers of enteral devices are phasing out their production of older-style enteral connectors in North America to improve patient safety, a trade group says.The Global Enteral Device Supplier Association says its members and affiliates in the enteral feeding device market are increasingly converting to ENFit connectors that comply with the International Organization for Standardization’s ISO 80369-3 standard and they are updating their timelines for the phase-out of the older-style devices.The trade group says the industry’s switch to ENFit connectors will reduce the “risks of potentially fatal medical device misconnections and minimize unintentional disconnections.” And the use of one universal technology should also mitigate supply-chain interruptions for enteral small-bore connectors, the group said. '},

{'identifier': 'https://www.fdanews.com/articles/topic/106?page=5',

'title': 'FDA Provides Update on Celltrion’s Recall of Some Lots of its COVID-19 Test',

'url': 'https://www.fdanews.com/articles/207041-fda-provides-update-on-celltrions-recall-of-some-lots-of-its-covid-19-test',

'date': '21-03-2022',

'keywords': 'recall',

'content': 'The FDA has issued on update on Celltrion’s Feb. 28 recall of specific lots of its DiaTrust COVID-19 Ag rapid test, deeming it a Class 1 recall because of the risk of serious injury or death.The reason for the recall is a high number of false-positive reports and unauthorized shelf life labeling. The 45,500 affected products with the product code 83QKP were distributed from June 2 to Dec. 21, 2021.The FDA says that although it has not received any reports of injuries, adverse health consequences or death due to use of the affected test kits, “false-positive or false-negative results from improper use of these tests could lead to further exposure of uninfected individuals to the SARS-CoV-2 virus.The agency also noted “serious injury risks if someone who is not trained to collect a nasopharyngeal swab sample attempts to do so.” '}],

[{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'Notified body update dampens hopes of near-term surge in IVDR capacity',

'url': 'https://www.medtechdive.com/news/notified-body-update-ivdr-mdr/621238/',

'date': '30-03-2022',

'keywords': 'notified body',

'content': 'The European Commission provided an update on the progress of notified body applications under the new regulations, revealing a growing pipeline of submissions that are approaching medical device designation but little hope of a near-term surge in in vitro diagnostic capacity.\xa0The Commission\'s March 21 update of the notified body pipeline reveals limited progress of the push to add more organizations capable of certifying products under the In Vitro Diagnostic Regulation.At the time of the December update, there were six notified bodies designated under IVDR.\xa0Another was in the final stages of the process, with\xa0designation and its addition to the EU\'s New Approach Notified and Designated Organizations (NANDO)\xa0database as the only two remaining steps.\xa0While that suggests the addition of a seventh IVDR notified body is on the horizon, there is then a gap back to the next organizations coming down the pipeline. Two other notified bodies have progressed to the joint assessment team corrective action and preventive action (JAT CAPA)\xa0review stage since December, but none have made it past.\xa0\xa0The early-stage pipeline has made little progress since December. One more notified body has applied, bringing the total up to 18, but the numbers for the first few steps in the process are the same as they were in December.\xa0As was the case in December, 12 notified bodies, including all those that have progressed further down the pipeline, have completed an onsite review by a joint assessment team (JAT). Ten notified bodies have received the final corrective action and preventive action (CAPA)\xa0review, up two from December.The upshot is the problems that led the EU to switch to a staggered rollout of IVDR are unlikely to change this year, unless there is a sharp acceleration of the designation process.The Commission proposed longer IVDR transition periods because of the "grave shortage of notified body capacity" that was made worse by the fact all the designated notified bodies were concentrated in three countries. The lack of progress means those issues may remain in place as the waves of IVDR deadlines approach.\xa0When the Commission shared an update late last year, it revealed that seven notified bodies were at the JAT CAPA\xa0plan review stage for designation under the Medical Device Regulation. Overall, 36 notified bodies had reached that stage, 27 of which had progressed to the next step and 25 of which had completed the process and had their information uploaded to the NANDO database.The latest update, which covers the situation as of March 21, reveals a clutch of notified bodies has now cleared the JAT CAPA review stage, putting them a handful of steps from the end of the MDR designation process. The current count shows another three notified bodies have advanced to the final report stage over the past few months.\xa0One of those notified bodies is still at the final report stage but the other two have made more progress, with one at the JAT final opinion step and the other designated and awaiting entry to NANDO. The recent progress suggests the pool of medical device designated notified bodies in NANDO, which has increased by two to 27 since December, will swell further over the coming months.\xa0The two recent additions to NANDO include a Polish notified body, meaning MDR organizations from 18 countries are now in the database. The geographic concentration of notified bodies in parts of Europe has been a concern because small and medium-sized companies are perceived to prefer to work locally.\xa0Progression of the MDR pipeline comes amid continued concern about whether the European Union has enough notified body capacity to ensure the smooth implementation of the regulation. Last month, France\'s Snitem and Germany\'s BVMed, leading medtech trade associations that cover more than half of the EU medical device market, called for the extension of the MDR transition period to avoid a "collapse in patient care."According to the trade groups, fewer than 1,000 of the 25,000 required certificates have been issued. The trade groups argue that, with more products to be certified and more extensive document checks needed, the pool of 27 notified bodies falls well short of the capacity needed to avoid disruption.\xa0The concerns echo those raised since the EU delayed the MDR start date by one year in response to the pandemic but left the end of the transition period unchanged, thereby averting a near-term threat but potentially storing up trouble for later.Notified body trade association Team-NB has repeatedly raised concerns about the transition period, most recently in December, when it warned the industry will face an "extreme bottleneck" when a large number of Medical Device Directive certificates expire in 2024.'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'FDA asks Congress for 14% bump in device budget for supply chain, cybersecurity programs',

'url': 'https://www.medtechdive.com/news/fda-congress-device-budget-supply-chain-cyber/621156/',

'date': '29-03-2022',

'keywords': 'device',

'content': 'The FDA is requesting an overall budget of $8.4 billion in fiscal year 2023, a nearly 34% increase over the FY 2022 appropriated funding level. For the devices program, the FDA is asking for roughly $698 million, with approximately $466 million from the budget authority and $232 million in user fees.The agency\'s request for more budget authority from Congress is split fairly evenly between money for medical product safety and crosscutting, a term that captures work such as capacity building and inspection activities that span multiple departments. FDA Commissioner Robert Califf in a statement said the budget request is critical as the agency continues to work on a wide range of COVID-19 and non-coronavirus priorities, with a focus on some of the most urgent needs including medical device safety and security.At $31.4 million, the safety program is in line to receive slightly more money, reflecting the fact that it covers the single biggest change in FDA\'s medical device spending plans for fiscal 2023, namely RSCSP. The budget proposes investing $21.6 million in the program."This funding will provide resources that will enable establishment of a permanent program for U.S. supply chain resilience for medical devices for the first time. The establishment of a permanent device shortages program will help ensure U.S. patients and health care providers have access to the critical devices they need and help reduce U.S. dependence on devices from other nations by enhancing CDRH\'s capacity to enable rapid intervention to prevent and mitigate supply chain interruptions," the FDA wrote in its budget justification.The agency envisages RSCSP using "state of the art supply chain intelligence for predictive modeling, early signal detection and continuous surveillance"\xa0as part of a push to establish preventative measures that make the supply chain more resilient by enabling the agency to avert shortages before they occur.The FDA said the funding is critical to reducing or eliminating the risk of medical device shortages experienced during the COVID-19 pandemic in order to ensure the U.S.\xa0is better prepared for future public health emergencies.\xa0The RSCSP funding covers 18 full-time equivalents (FTEs), representing more than one-third of the 48 staff FDA plans to add in fiscal 2023. FDA plans to add six FTEs if it secures its requested $5 million funding boost for its cybersecurity program. The funding boost will bring FDA\'s total medical device cybersecurity budget up to $5.5 million.\xa0FDA wants to take on the six FTEs to "increase its internal capabilities through the recruitment and development of cyber experts to support the review of medical devices and assure that they are highly resistant to security breaches before being marketed."\xa0The funding will also enable the agency to administer grants and contracts "to develop infrastructure geared towards addressing emerging challenges in order to strengthen cybersecurity resilience in the medical device ecosystem, such as tools to track vulnerabilities associated with devices."The FDA wants to establish "tangible measures"\xa0of cybersecurity such as time from vulnerability identification to remediation.In addition, the FDA is asking Congress for the "express authority"\xa0to require premarket submissions to include evidence of "reasonable assurance of the device\'s safety and effectiveness for purposes of cybersecurity"\xa0and for devices to "have the capability to be updated and patched in a timely manner."Currently, there is no statutory pre- or post-market requirement that expressly requires medical device manufacturers to address cybersecurity, according to the agency. The FDA\'s FY 2023 budget includes a legislative proposal that "seeks additional authorities across the lifecycle of the device and includes elements such as a software bill of materials."The FDA is also seeking a further $26.4 million and 24 FTEs in relation to crosscutting work such as capacity building and inspection activities that span multiple departments.Pay costs are the biggest crosscutting budgetary line item, with the agency calculating that the 4.6% cost of living adjustment and 1.1% increase in retirement contributions will require an additional $8.1 million for the devices program.\xa0Most of the crosscutting FTEs are earmarked for inspection activities. The FDA plans to take on 14 FTEs to "support capacity building towards an advanced, highly trained investigators capable of analyzing available data to increase the efficiency and productivity of our inspection operations."'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'MDR updates safety, clinical performance requirement for high-risk devices',

'url': 'https://www.medtechdive.com/news/mdr-safety-performance-requirement-high-risk-devices/621089/',

'date': '28-03-2022',

'keywords': 'device',

'content': 'MDCG, which advises the European Commission on medical device matters, created the 2019 guidance to help manufacturers and notified bodies comply with a transparency provision of MDR. By requiring the creation, validation and publication of summaries of safety and clinical performance (SSCP), MDR seeks to provide healthcare professionals and patients with "an important source of information"\xa0on the performance of high-risk medical devices.The first revision of the guide retains all of the information provided in 2019. The main changes are the addition of a new paragraph on reference numbers and a related update to a summary template.MDCG\'s additional paragraph states: "The manufacturer will assign to the SSCP an identifier (reference number) that within the manufacturer\'s management system is unique to that SSCP and will remain the same for the entire lifetime of the SCP. In combination with the manufacturer\'s (single registration number)\xa0this will allow for the unique identification of the SSCP in EUDAMED and in EU."The updated template features "manufacturer’s reference number for the SSCP"\xa0at the top of the list of elements MDCG recommends manufacturers include in their summaries. The rest of the list is the same as the 2019 guide. MDCG also revised another section so it states the summary can be associated with one or multiple basic unique device identification - device identifiers (UDI-DIs). The 2019 guide states the SSCP is "associated to one unique Basic UDI-DI."MDCG\'s update comes against a backdrop of continued debate about the implementation of MDR. Earlier this month, medtech trade groups in France and Germany, whose members make up more than half of the EU market, called for an extension of the MDR transition period to avoid a "collapse in patient care."\xa0The trade groups called for a two-year extension for the Class III and implantable products covered by the MDCG guide, plus a four-year delay for all other products. '},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'FDA sets terms for MDUFA V agreement',

'url': 'https://www.medtechdive.com/news/fda-mdufa-v-agreement/620888/',

'date': '23-03-2022',

'keywords': 'mdufa',

'content': 'Industry groups largely supported MDUFA V, though it took months of contentious talks to reach an agreement. The Medical Imaging and Technology Alliance urged swift passage of the proposal on Wednesday, after the FDA had shared a commitment letter with its goals on Tuesday afternoon.\xa0"Through over a year and a half of negotiations, we have agreed to a good deal for the FDA, industry and most importantly for patients," MITA Executive Director Patrick Hope said in a news release. "The agreement will help get the FDA back on track after several years of grappling with the COVID pandemic and introduces new accountability measures related to hiring targets, accrual and use of carryover balance."AdvaMed CEO Scott Whitaker also applauded the new performance requirements for the FDA, adding that the agreement would hold innovators to high standards for communicating device performance to the agency.“The result will be more timely approval of medical technology earning the FDA’s global gold standard of safety and effectiveness,” Whitaker said in an emailed statement. “AdvaMed looks forward to public and congressional consideration of the agreement.”Earlier this month, MedTech Dive reported that the FDA and industry had reached a consensus, months after the Jan. 15 deadline to send an agreement to Congress. The new agreement includes accountability measures that might have helped win over industry. For instance, the FDA must meet certain hiring targets, and is also limited to 13 weeks of operating reserves in its carryover balance.\xa0Jeff Shuren, director of the FDA\'s Center for Devices and Radiological Health,\xa0said in a news release\xa0that the new agreement "represents a substantial investment in the future of the agency\'s medical device program and would provide for important improvements, including new hiring targets, greater engagement with developers of innovative technologies based on lessons learned from the pandemic, broadened international harmonization efforts and expanded opportunities to ensure patient perspectives are an integral part of medical device development."This comes as the FDA has struggled to meet its performance targets in recent months, as a significant portion of the agency\'s resources has been dedicated to the COVID-19 pandemic. The agency met its performance goal for 73% of applications in 2021, falling to a new low\xa0against its MDUFA IV target.\xa0For premarket approval submissions received in 2023 and 2024, the FDA has set a goal of 290 days to reach a decision. Starting in 2025, that will shorten to 285 days.For 510(k) submissions, the FDA has set a goal of 128 days for 2023,\xa0shortening to 112 days starting in 2025. The FDA has also committed to communicate if an application has been accepted within 15 days of pre-submission.\xa0As part of the agreement, the FDA set minimum hiring goals for the next three years. If it misses these goals by more than 15% in 2023, or 10% in the following years, then it must adjust its fees accordingly.For 2023, the FDA plans to hire 144 people. In 2024, it plans to make 42 new hires, and in 2025, it expects to make 24 hires.\xa0The FDA also plans to launch a total product lifecycle advisory program (TAP), which will be funded in part by the agreement. It\'s intended to enable earlier and more frequent communication between the agency and product sponsors, and make the premarket review process more efficient. The agency will start with a soft launch of the program next year, starting with 15 products, with plans to gradually scale up to enroll 100 products per year. To start, the FDA will focus on products that have received a breakthrough designation.\xa0This article was updated to include a statement from AdvaMed.'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'Another Philips ventilator recall gets Class I label from the FDA',

'url': 'https://www.medtechdive.com/news/another-philips-recall-class-i-label-fda/620854/',

'date': '23-03-2022',

'keywords': 'recall',

'content': 'The quality standards of Philips\'\xa0respiratory business have been in the spotlight since the company began recalling millions of sleep apnea devices and ventilators over concerns the sound abatement foam may break down and expose patients to toxic chemicals.A separate recall of V60 ventilators started weeks later in response to the discovery the devices may provide the patient with a lower oxygen flow rate. The problem caused 25 injuries at the time of the recall.Philips began the latest recall of V60 ventilators in January. The recall, which is distinct from the flow rate problem, covers 1,511 devices distributed over a two-week period last summer. Philips put the devices together using an expired adhesive. FDA set out the potential implications of that quality failure in its notice to communicate the Class I recall.\xa0\xa0\xa0"If the adhesive fails, it could cause a capacitor support bracket to become loose and potentially damage the capacitors, which could cause the ventilator to stop providing ventilation to the patient. This failure may cause an alarm to notify the health care provider, or it may not sound any alarm at all,"\xa0the agency wrote.The effect of the cessation of ventilation on the patient will depend on whether an alarm sounds. In the worst-case scenario, the lack of an alarm could leave the patient deprived of oxygen for "an extended time,"\xa0FDA said, potentially leading to serious adverse health consequences and death.Philips asked users of affected devices to connect their ventilators to remote alarm systems, if available, when it first communicated the problem to customers in January. The remote alarm provides a backup that should sound even if the ventilator\'s primary alarm system fails to go off.Other recommended precautions include the provision of external oxygen monitoring to minimize patient risk if the device fails.\xa0News of the recall comes months after Philips expanded its program to repair and replace devices that use the potentially harmful sound abatement foam. '},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'FDA labels Philips 2018 field correction for ventilators a Class I recall',

'url': 'https://www.medtechdive.com/news/fda-labels-philips-correction-class-i-recall/620804/',

'date': '22-03-2022',

'keywords': 'recall',

'content': 'In June, Philips initiated a recall of sleep apnea and ventilator machines due to safety risks associated with polyester-based polyurethane (PE-PUR) foam used to dampen the sound of the devices. The foam was found to break down over time and be ingested or inhaled by users, possibly exposing them to toxic chemicals.The recall was labeled a Class I event by the FDA and ultimately impacted over 5 million devices.The FDA\'s most recent action is now labeling the 2018 corrective action from Philips a Class I recall; the agency created an entry in its recall database on March 18.The agency discovered the corrective action during a recent facility inspection following the June recall.In the FDA\'s facility inspection form, called a Form 483, the agency wrote that the company did not notify the agency despite having reports of foam breaking down in Trilogy and other machines as early as 2014.The field correction was initiated in response to several complaints and at least one failure from a Trilogy machine caused by foam degradation, and the foam was later found to be "mutagenic, cytotoxic, carcinogenic, and non-biocompatible.""Additionally, per a complaint analysis performed by this firm on 04/09/2021, this firm received approximately 30 complaints related to foam degradation of Trilogy devices from 2014 to 2017, and approximately 80 complaints related to degraded foam on other [continuous positive airway pressure] and [bilevel positive airway pressure] devices from 2014 to 2017," the FDA stated in the November document.Risks to patients from the breakdown of the PE-PUR foam would ultimately spur the June recall.Philips said that in response to the agency\'s Form 483, a "retroactive report was made to the FDA about the 2018 Preventative Maintenance protocol update."According to the March 18 database entry, the Class I recall impacts Trilogy 100/200, Garbin Plus, Aeris and LifeVent Continuous Ventilators machines.\xa0The company\'s response to the recall of millions of devices has been criticized by both patients and the FDA. On March 10, the FDA published orders for the company to improve its communication efforts after finding that patients and suppliers were unaware of the recall after it was initiated, calling Philips\' previous communication efforts "inadequate."Philips is also facing about 100 class-action lawsuits as of Dec. 31, as well as approximately 120 personal injury lawsuits in the U.S. which were consolidated into multi-district litigation in the U.S. District Court for the Western District of Pennsylvania in October.As of January, the company has set aside 725 million euros to address the recall, which was equal to about $825 million at the time of the announcement.'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': "Dexcom's hospital glucose monitor leads latest FDA breakthrough designations",

'url': 'https://www.medtechdive.com/news/dexcom-breakthrough-designation-hospital-glucose-monitor/620774/',

'date': '22-03-2022',

'keywords': 'designation',

'content': 'Dexcom has led the latest batch of FDA breakthrough device designations, securing the regulatory privileges\xa0for a version of its continuous glucose monitor technology designed for use in hospital settings.\xa0After the start of the COVID-19 pandemic, the FDA issued guidance allowing glucose monitors indicated for home use to be used in a hospital setting, letting patients track and report their own blood glucose levels to reduce health care workers\'\xa0exposure to the virus.\xa0Now, Dexcom is seeking clearance for its CGMs to be used in a hospital setting.\xa0The breakthrough designation covers a small, wearable sensor that continuously measures glucose levels and a linked transmitter that sends the data wirelessly to a smart device. In doing so, the system provides real-time glucose data without needing to take samples using finger sticks. Users can set customizable alerts for when a patient has dangerously high or low blood glucose levels.\xa0Those features have enabled Dexcom to capture a slice of the outpatient market for CGMs. In recent years, Dexcom and its partners have laid the groundwork for the expansion of the use of the device into hospital settings, notably when FDA relaxed the rules on its use by inpatients during the pandemic.\xa0"In our extensive use of Dexcom CGM in our hospitals as part of exploratory studies over the last seven years, more than 800 of those patients treated during the pandemic, we have found that the device improves glucose control without any increased risk in hypoglycemia," Athena Philis-Tsimikas, an endocrinologist and corporate vice president for the Scripps Whittier Diabetes Institute in San Diego, said in a statement.\xa0Dexcom is one of a handful of companies to disclose breakthrough device designations so far this month. Insightec received the status for its Exablate Neuro system in the treatment of non-small cell lung cancer (NSCLC). The device uses noninvasive, low-intensity focused ultrasound to try to open up the blood-brain barrier, thereby enabling treatments to reach the sites of hard-to-treat NSCLC metastases.Insightec disclosed the breakthrough designation alongside news that FDA has granted its request to trial the device in combination with Merck\'s checkpoint inhibitor Keytruda in NSCLC that has metastasized to the brain, and to enhance the efficacy of liquid biopsy for recurrence monitoring of patients with primary brain cancer. The device is already approved for use in the treatment of essential tremor and Parkinson\'s disease.\xa0FDA granted breakthrough status to Merit Medical Systems\' Embosphere microspheres for use in the genicular artery embolization (GAE) of patients with symptomatic knee osteoarthritis. Surgeons perform GAE to reduce blood flow to the knee and thereby reduce pain and disability caused by inflammation. Merit\'s microspheres are already used to occlude blood vessels for other purposes.\xa0\xa0AltPep received breakthrough status for a blood test to detect Alzheimer\'s disease. The SOBA-AD assay is designed to detect toxic forms of the amyloid-beta peptide that aggregates in patients with the disease at an early stage in the progression of Alzheimer\'s. AltPep\'s long-term vision is to detect the disease even before symptoms occur and thereby potentially enable treatments that limit cognitive decline.\xa0\xa0\xa0CardioStory secured the FDA designation for a non-invasive filling pressure measurement and monitoring platform for use in heart failure patients. The breakthrough status follows the completion of a study that found the noninvasive option had 89% accuracy compared to the invasive, gold-standard approach to the measurement of pulmonary capillary wedge pressure.Finally, Georgia Institute of Technology hailed the contribution of its researcher Omer Inan and Emory University psychiatrist Douglas Bremner to a breakthrough designation for electroCore\'s non-invasive vagus nerve stimulation device to reduce PTSD symptoms. The company disclosed the breakthrough status in January.'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': "French, German medtech groups call for at least 2-year extension of MDR's transition period",

'url': 'https://www.medtechdive.com/news/french-german-medtech-groups-extension-mdr/620551/',

'date': '17-03-2022',

'keywords': 'medtech',

'content': 'The French and German trade groups made the case that despite the MDR going into effect last year, key parts of the necessary infrastructure are still not fully operational,\xa0creating challenges in particular for small- and medium-sized medtech companies that are reaching the limits of what is feasible when it comes to the certification of new and existing devices.Of the approximately 25,000 required certificates that have to be transferred to the MDR, less than 1,000 have so far been issued, the trade groups noted, adding that the average duration of the certification process is approximately 18 months.With the MDR transition period ending on May 26, 2024, the trade groups warned that by the third quarter of 2022 business decisions must be made as to which products must be withdrawn from the EU market.\xa0\xa0\xa0"With more products to be certified in a shorter period of time and more extensive documents to be checked, the current capacity of the currently 27 notified bodies is not sufficient and is far from the capacity actually required," according to BVMed and Snitem.\xa0"We are running out of time. The situation worsens dramatically. A collapse in patient care must be prevented."However, extending the MDR transition period is not the only fix that BVMed and Snitem want to see. The device associations contend it is critical that notified bodies continue to "massively expand their existing capacity" and there must be equal access to NBs for all manufacturers.To address the backlog in the certification of existing products, BVMed and Snitem want to see the designation period for notified bodies shortened, ongoing assessments streamlined and incentives set for further applications.\xa0BVMed and Snitem aren\'t the only European medical device groups sounding the alarm about MDR\'s\xa0potential to disrupt product supply due to issues with the EU\'s infrastructure.\xa0MedTech Europe for some time has warned that although the new regulatory regime reached its date of application in 2021, significant challenges remain unresolved that could negatively impact the medtech sector including limited capacity among notified bodies, especially for certification of new and innovative devices."Roadblocks will continue to limit the sector\'s ability to seamlessly supply certified devices under the new rules. This is especially true for many small and medium enterprises, who contribute a significant portion of Europe\'s medical device innovations,"\xa0MedTech Europe said in May 2021 when MDR went in effect.'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'FDA identified 28 suppliers unaware of Philips sleep device recall',

'url': 'https://www.medtechdive.com/news/fda-identified-suppliers-unaware-philips-recall/620482/',

'date': '16-03-2022',

'keywords': 'recall | device',

'content': 'Last Thursday, the FDA released an order directing Philips to notify all of its customers regarding the recall of sleep apnea and ventilator machines, after the agency determined the company had failed to adequately communicate the recall and the health risks facing patients if affected devices were still used.The order comes nine months after Philips initiated its recall of over 5 million devices, and nearly one year after the company publicly acknowledged product safety risks with certain machines.In a six-page letter to Philips, the FDA said that the order comes due to "the significant period of time that has transpired since the initiation of the recall, and Philips\' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons … who should be notified, of the recall and the health risks presented by the Recalled Products."The FDA said that in an assessment of Philips\' communication efforts, the agency identified 28 suppliers of devices that were unaware of the recall after it was initiated.Michael Heyl, a partner with the law firm Hogan Lovells, wrote in an email that the FDA\'s decision to issue this type of order is "fairly rare.""Typically when FDA has a concern with a manufacturer\'s voluntary recall, or how a recall is being handled, there will be a discussion with the manufacturer," Heyl wrote in the statement. "In these discussions, FDA will present its perspectives and concerns and make recommendations as to how to address these concerns."The FDA is issuing its order under section 518(a) of the Federal Food, Drug, and Cosmetic Act, which gives the agency the authority to order a manufacturer to provide notification if a device is determined to be an unreasonable risk of substantial harm to the public health and the notification can help eliminate risk, according to the FDA\'s announcement.Philips initiated a recall in June due to health risks associated with the use of certain sleep apnea and ventilator machines. Philips found that that foam used to dampen the noise of machines could break down and the particles can be inhaled or ingested by users, possibly exposing them to toxic chemicals.The company has come under fire for how it has handled the recall, and now the FDA\'s order adds to the hundreds of consumer and commercial lawsuits Philips is facing.The agency listed out several directives and recommendations for how the company can improve its recall communication process and how it should improve its repair and replacement program for impacted devices.Now that the FDA has issued an order, Philips will "need to implement action in response to the order within the timelines prescribed," Heyl said. However, Heyl added that any enhancements to Philips\' recall process overall will be up to the company to change.The recall adds to several other product safety events in the medical device industry, which led to the FDA holding two public meetings reviewing the device recall process, and it is emblematic of concerns with the recall process in general.In an October meeting, the lack of effective communication to patients was a topic that came up multiple times, and it is a key critique of product safety and supply chain experts.The lack of a clear requirement or accountability for patient communication, experts argue, can lead to patients never learning that a device they use or have had implanted is part of a recall, an issue that has come up with Philips.Along with patients and customers not being aware of the recall, the FDA wrote in its letter to the company that "it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products."To determine how the recall process was going, the FDA conducted its own test and found that consignees,\xa0or suppliers of devices, were not aware of the recall after it began.The agency reached out to 182 suppliers and found that 28 were not aware of the recall, according to the FDA\'s letter. Suppliers were selected because "if consignees are unaware of the recall and the health risks posed by the Recalled Products, it is likely that their customers are also unaware."The FDA emailed Philips about the results of their assessment on Sept. 8 and Oct. 29. However, Philips did not respond to either email, according to the agency.The company said during a Nov. 22 call with the FDA that there was "delivery confirmation" for 23 of the 28 consignees and provided a spreadsheet identifying this information, according to the FDA."However, that spreadsheet did not include the date that each confirmation was received, nor did Philips indicate whether the consignees identified by FDA had been sent notification before, or only after, they had been identified by FDA as being unaware of the recall," the letter stated.The FDA added that delivery confirmation does not mean that someone or some entity has actually received the notice and information in the notice, adding that firms "demonstrate the effectiveness of its recall communications through evidence more meaningful than a delivery confirmation receipt, such as a returned response form or a documented telephone conversation."Philips said in a press release that it has reached the "vast majority" of users in the U.S. and 2.6 million devices have been registered. In an emailed statement, however, the company would not comment on how many remaining users there were to reach in the U.S. or how many total affected devices there are in the U.S.A company spokesperson said in a statement emailed Monday to MedTech Dive that the company is also working with international regulators about the recall.Philips estimates that the repair and replacement program will be completed in the fourth quarter. As of January, the company has set aside 725 million euros to address the recall, which was equal to about $825 million at the time of the announcement.The FDA\'s main directive is for Philips to reach out to all of its customers regarding the recall and the health risks of using the affected devices.The agency said that Philips can get the contact information for patients, consumers or providers that received a product from a particular consignee, and then Philips can contact each customer within 30 days of receiving the information.The second option laid out by the FDA was that Philips receive confirmation from consignees that they have contacted every customer within 30 days of receiving Philips\' notification.The FDA also outlined several recommendations for Philips, such as developing a strategy to improve patient and customer registration of devices online and regularly update the agency with new registration figures, improving the sharing of information about the recall and repair and replacement program, as well as providing "detailed information" regarding the replacement process such as any costs that may come with replacing a device.The agency also recommended that the company responds within 24 hours to customers who reach out to a recall-assistance phone number.Hogan Lovell\'s Heyl said that companies generally work with the FDA to address recommendations."If there is disagreement with an FDA recommendation, a company should promptly indicate this to the agency with its rationales or arguments supporting its position or strategy," Heyl said. "The more fact or evidence-based the position, or the more data that there are to support the company\'s position, the better the likelihood that FDA will agree and either support modified language or drop the recommendation altogether."Philips has within 45 days of the order to comply.\xa0If companies do not comply with FDA orders in general, Heyl said, there are multiple "enforcement options available," ranging from further talks with the company to a warning letter, or even criminal fines and penalties depending on the circumstances.A Philips spokesperson reiterated Monday that the company is complying with the FDA\'s requests."There isn\'t anything in the Order that we have already been doing or are about to do," the spokesperson wrote in the emailed statement. "We therefore expect to fully comply with the Order."'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'US replaces EU as priority market for medtech industry: survey',

'url': 'https://www.medtechdive.com/news/us-replaces-eu-priority-market-medtechs/620450/',

'date': '16-03-2022',

'keywords': 'medtech',

'content': 'The past few years have seen regulators on both sides of the Atlantic change their approach to medtech. The biggest changes have happened in the EU, where MDR and the In Vitro Diagnostic Regulation are redefining what it takes to bring products to market in the region.\xa0At the same time, FDA has set the target of making the U.S. the priority market for developers of novel devices.In its most recent assessment, FDA found almost two-third of manufacturers of novel technology devices plan to bring their products to the U.S. first or in parallel with other major markets. The BCG report adds to evidence that FDA is on course to achieve its objective.\xa0\xa0The shift in focus from the EU to the U.S. appears to have at least as much to do with what Europe has done to alienate the industry as what FDA has done to woo it. For 23% of companies with CE marks, the EU has now fallen behind Japan and China on the list of priority markets, reflecting concerns about the impact of MDR and other factors."Respondents overwhelmingly view new MDR rules as complex and unpredictable, making it less appealing to develop and launch novel products in Europe. Other factors, including Brexit and intense reimbursement pricing pressure, may also reduce the attractiveness of pursuing the CE mark,"\xa0the BCG report states.Only 22% of respondents said the EU pathway for regulatory approval of standard medical technology is predictable. The figure for the U.S. was 62%. There is still room to improve for FDA, particularly with 33% of respondents viewing its digital product pathway as predictable, but there was broad support for some of its key initiatives and a perception that it now offers a clearer path to market than the EU.In the survey, 79% of respondents strongly agreed or somewhat agreed that the FDA is responding effectively to advancements in medical technology. When its comes to artificial intelligence and machine learning, surveyed executives contend U.S. regulators also have the advantage.The BCG report notes that medtech companies are developing AI/ML products at an accelerating rate."Of the 343 approvals of such products by the FDA since 1997, more than half occurred in 2019 and 2020. Because they are innovative, these products demand greater expertise on the part of reviewers and more regulatory clarity for companies,"\xa0the report states.\xa0Survey respondents praised FDA\'s breakthrough device designation program, with 88% of people saying the guidance is at least somewhat clear and 75% expressing the belief that it will lead to earlier patient access. More than half of respondents believe the program supports more flexible study design.'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': "Steep drop in medical device reports on Bayer's Essure in 2021, FDA data show",

'url': 'https://www.medtechdive.com/news/drop-in-device-reports-bayers-essure-2021-fda/620380/',

'date': '15-03-2022',

'keywords': 'device',

'content': 'Bayer stopped selling Essure, an implant designed to provide a permanent birth control option, late in 2018. The withdrawal followed tens of thousands of reports of complications, although Bayer stood by the safety of the device and framed its action as a business decision. While it is now years since Essure was sold in the U.S., the analysis of data on the safety of the device continues apace.\xa0FDA updated its webpage on problems with Essure on Monday. The webpage now features details of the agency’s analysis of the medical device reports it received in relation to Essure last year. FDA analyzed the data in the context of reports on the safety of the device going back to when it came to market 20 years ago.Having received 15,000 reports in 2019 and 16,000 reports in 2020, FDA received just 3,701 reports related to Essure last year. Bayer submitted 98% of the Essure reports received by the agency last year. The company has been the main source of Essure reports to FDA since 2016.FDA said the "nature and severity of the reports in 2021 remain consistent with prior years." Across the entire 2002-2021 dataset, the most reported patient problems were pain/abdominal pain, heavier menses/hemorrhage/menstrual irregularities, foreign body/device fragment in patient and perforation.There are now 95 reports coded by the submitter as death in the dataset through Dec. 31, up one from last year. The additional report is one of 29 that "reference information on deaths posted in social media or other media outlets." FDA said, "it is difficult ... to determine whether the device caused the death with only the information provided in the report."\xa0Bayer has now completed the monthly reports of the adverse event information it received between November 2016 and November 2020 as part of litigation. FDA summarizes the 57,802 reportable events, the final set of which were published last year, on its webpage giving an overview of problems with Essure.'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': "Apyx's surgical device gets FDA warning on off-label skin procedure use",

'url': 'https://www.medtechdive.com/news/apyxs-surgical-device-gets-fda-warning-on-off-label-skin-procedure-use/620379/',

'date': '15-03-2022',

'keywords': 'device',

'content': 'Dermal resurfacing is a long-standing target market for Apyx, which filed for clearance in the indication in 2018 only to withdraw the submission the following year. The company generated more data in the indication and recently refiled for 510(k) clearance. Throughout that time, the device was available in the U.S. for electrosurgical cutting, coagulation and ablation of soft tissue.The FDA now has evidence physicians have used the device off-label. The reports to the agency describe "serious and potentially life-threatening adverse events after the device was used for aesthetic skin procedures."\xa0The list of adverse events submitted to FDA includes nerve damage and significant bleeding.In response, the FDA has told healthcare providers the device is not cleared or approved for any aesthetic skin procedures and off-label use in that context may result in serious and potentially life-threatening adverse events.\xa0"Do not use the Renuvion/J-Plasma device for dermal resurfacing or skin contraction, alone or in combination with liposuction,"\xa0the agency warned healthcare providers. "If you are performing an aesthetic procedure, inform your patient which devices you plan to use."The FDA also is advising consumers who are considering undergoing aesthetic skin procedures or liposuction to ask their providers whether they plan to use the Apyx device.\xa0Apyx CEO Charlie Goodwin said in a statement\xa0that the company is aware that some of its products are used off-label for dermal resurfacing procedures but sought to distance the business from those practices.\xa0"We do not and will not promote the use of our products – or train physicians – for these procedures until we receive clearance from the FDA. Our labeling specifically warns against the use of our products for this indication as well. We support the FDA\'s focus on ensuring that healthcare providers and patients understand the safe and proper use of our products,"\xa0Goodwin said.According to Goodwin, Apyx has submitted 90 medical device reports related to subdermal coagulation since the beginning of 2017. The company submitted 32 reports last year, up from 15 in 2020. Goodwin contends the increase factored into the FDA\'s decision to post the notice. The number of subdermal coagulation procedures performed with the Apyx products more than doubled from 2020 to 2021.The CEO added that Apyx\'s\xa0two pending 510(k) premarket notifications remain under review by the FDA, which "are intended to obtain a general indication for use of the Renuvion Dermal handpiece in dermatological procedures requiring ablation and resurfacing of the skin, and a specific clinical indication for treating wrinkles and rhytids."'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': "FDA orders Philips to notify customers about sleep device recall due to 'inadequate' prior efforts",

'url': 'https://www.medtechdive.com/news/fda-orders-philips-notify-customer-recall/620250/',

'date': '11-03-2022',

'keywords': 'recall | device',

'content': 'It has been almost one year since Philips publicly acknowledged product safety issues with certain sleep apnea and ventilator machines.The company in June officially initiated a recall due to foam used to dampen sound in machines breaking down, creating the risk of particles being inhaled or ingested by users and possibly exposing them to toxic chemicals. The recall ultimately affected more than 5 million devices.The FDA wrote in Thursday\'s statement that once broken down, the foam can result in serious injury, including injuries that can be life-threatening, can cause permanent impairment and/or require medical intervention to prevent permanent injury.The agency ordered Philips to notify all device users, durable medical equipment suppliers, distributors, retailers and healthcare providers that prescribe the products about the health risks posed by the foam in recalled products.The FDA also ordered Philips to maintain "prominently displayed information"\xa0on their main webpage for the recall\xa0regarding the risk of using ozone cleaners on the recalled devices, which the company has attributed as one cause of the foam breakdown.Other orders from the FDA include providing a link to testing done on devices using the foam."The information currently available on Philips\' website is vague, and does not provide healthcare providers with the facts necessary for them to make informed decisions regarding the risks associated with the continued use of the Recalled Products for their patients," the agency stated in its letter.The company has 45 days from the time of the order to comply."We are doing and will continue to do everything possible to support our customers, clinicians and their patients, and to accelerate the replacement actions," a Phillips spokesperson said in an emailed statement. "We have been in dialogue and cooperating with the FDA from the start of the recall. There is nothing in the Order that we have not already been doing and are about to do."Philips said in a Thursday press release that the company has reached "the vast majority" of the installed base in the U.S., resulting in the registration of 2.6 million devices. More than 650,000 replacement devices have been shipped to customers in the U.S. and the repair and replacement program is expected to be completed in the fourth quarter of 2022, according to the statement.The number of total impacted devices in the U.S. and how many remaining customers need to be reached was not provided in the statement.The recall could cost Philips hundreds of millions of dollars and it has opened up the market for rival ResMed, possibly permanently altering the competitive landscape. As of January, the company has set aside 725 million euros to address the recall, which was equal to about $825 million at the time of the announcement.The financial impact of the recall may grow as Philips faces lawsuits in and outside of the U.S.In its annual report released\xa0in February, Philips said that the company faced about 100 class-action lawsuits in the U.S. as of Dec. 31, 2021, that allege "economic loss and/or medical monitoring claims." In addition, the company also is facing approximately 120 personal injury lawsuits in the U.S. that were consolidated into multi-district litigation in the U.S. District Court for the Western District of Pennsylvania in October.The company and/or subsidiaries also are facing consumer class-action lawsuits in Australia, Canada and Israel."While the company believes it is probable that these lawsuits will in the aggregate lead to an outflow of economic resources for Philips Respironics or other Philips entities, given the significant uncertainty regarding the nature of the relevant events and potential obligations, the company is not currently able to reliably estimate the amount of the obligation associated with these various lawsuits," Philips said in its annual report.'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'FDA reaches MDUFA V agreement with industry',

'url': 'https://www.medtechdive.com/news/fda-reaches-mdufa-v-agreement-medical-device/620136/',

'date': '09-03-2022',

'keywords': 'mdufa',

'content': 'The road to hammering out a MDUFA V agreement has been a bumpy and contentious one. The FDA and the medical device industry often were at loggerheads\xa0over "fundamentally different"\xa0views during the months-long negotiations that got off to a late start in early 2021 due to the COVID-19 pandemic.The FDA, perhaps in an indication of that agency-industry divide,\xa0failed to send the final MDUFA V agreement to Congress by the Jan. 15 deadline. By comparison, the FDA\'s commitment letter\xa0to the pharmaceutical sector was published in August. However, both the agency and AdvaMed now can see the light at the end of the tunnel.The MDUFA V deal, which determines how much industry pays for FDA product reviews from 2023 to 2027 and what performance goals the agency will be measured against, in the end was about compromise, according to the industry source familiar with the negotiations."The sticking points weren\'t necessarily complicated so much as FDA being dug in on what they wanted and we were dug in on what we wanted. It took a while for some common ground to be found," the industry source said. "The final agreement is pretty consensus-focused and not one side dominating the other."One of the FDA\'s priorities that was ultimately included in the MDUFA V agreement was funding for the agency’s proposed total product lifecycle advisory program (TAP), which industry initially opposed.The agency pitched TAP as a way "to enable earlier, more frequent, and more strategic communication between FDA and sponsors, as well as to facilitate sponsors\' early engagement and coordination with external stakeholders that impact patient access to medical technologies, such as payors and physician professional societies."However, industry representatives in talks with the FDA questioned the need for the program and voiced their doubts about whether private payors would participate. In the end, the agency prevailed with some caveats.In the MDUFA V agreement, TAP will be funded as a pilot with a MDUFA IV carryover balance of $110 million and an additional $45 million from base funding,\xa0according to the industry source, who noted that there will be a pilot mid-point assessment and evaluation during MDUFA VI negotiations.The agreement also caps the FDA\'s MDUFA V carryover balances to three months reserve, similar to the way it is set up for the Prescription Drug User Fee Amendments (PDUFA), the source added. The use of funds would require "an alignment" and input from industry.Under the MDUFA V agreement, there are hiring targets established for the FDA, which was one of the requirements advocated for by industry. The agency must meet an 85% hiring target in fiscal year 2023 and a 90% hiring target in FY 2024.Last month, the FDA\'s Center for Devices and Radiological Health said its goal\xa0is to achieve at least 90% of its annual center-wide hiring targets in its 2023 to 2025 fiscal years. The commitment, which CDRH made in a report on its 2022-2025 strategic priorities, comes as the center\'s resources continue to be strained by a COVID-19 workload and follows MDUFA V talks that exposed industry concerns\xa0about the number of vacancies at the agency.AdvaMed\'s Whitaker in a statement on Wednesday thanked the FDA "for their commitment and hard work" throughout the MDUFA V negotiations process, adding that the medtech lobby is looking forward to "input and guidance from Congress on the agreement going forward."\xa0'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'FDA warns of cyber vulnerabilities in medical device software components',

'url': 'https://www.medtechdive.com/news/fda-cyber-vulnerabilities-PTC-Axeda-medical-device-software-/620075/',

'date': '09-03-2022',

'keywords': 'device | software',

'content': 'All versions of PTC\'s Axeda agent and desktop server are affected by the Access:7 cyber vulnerabilities, according to FDA\'s alert to device users and manufacturers. FDA warned that "successful exploitation of these vulnerabilities could result in full system access, remote code execution, read/change configuration, file system read access, log information access, and a denial-of-service condition."PTC in its public advisory said the vulnerabilities were discovered by research firm CyberMDX and reported through PTC\'s Coordinated Vulnerability Disclosure Program. Working together, the two companies investigated and implemented fixes for the vulnerabilities and then PTC "notified customers and guided their remediations ahead of disclosure."Accuray said\xa0it determined that the recently discovered Axeda vulnerabilities "affect" its products, but no exploitation has been reported. Bayer\'s website reported\xa0that the company has been "working with urgency to minimize any potential impact" to its customers and has "deployed a patch to all Bayer devices connected to VirtualCARE Remote Support," while injection systems "that have received this patch are no longer at risk for the vulnerability."GE Healthcare on its website said the company has performed impact and risk assessments, indicating that only a very limited number of its products are "potentially impacted by a subset of these vulnerabilities." Varian in a statement\xa0noted that its "cybersecurity experts continue to analyze and address potential impact to our products" from the Axeda vulnerabilities and "when appropriate, Varian provides updates to fix the vulnerability, or specific countermeasures for products where fixes are not yet available."Chris Gates, director of product security at medical device engineering firm Velentium, contends that remote desktop software is utilized in a lot of devices and it is going to be costly for manufacturers to fix all of them in the field."At what point are vendors such as PTC going to be liable for selling such insecure products? This isn\'t just a case of a missed vulnerability. The presence of hard-coded credentials shows a distinct disregard for creating a secure product. And, this is a remote desktop, one of the most targeted classes of products," Gates said.In response to a query from MedTech Dive, PTC declined to comment on the vulnerabilities of its Axeda agent and desktop server and instead pointed to its advisory.Mike Rushanan, director of medical security at consultancy Harbor Labs, contends that hard-coded credentials in particular – the software development practice of embedding authentication data such as passwords directly into the source code – are a significant cybersecurity risk."Manufacturers, especially medical device manufacturers, must not hard-code any credentials – passwords and cryptographic keys. And, they must force users to update default credentials immediately on first use," Rushanan said.Axel Wirth, chief security strategist of medical device cyber firm MedCrypt, called it "astounding" that nine years after CISA issued one of its early cybersecurity alerts calling out the risk of hard-coded passwords, the medtech industry is still seeing advisories that are related to hard-coded credentials.Becton Dickinson on Tuesday in a statement said it is "aware of and actively monitoring" vulnerabilities associated with PTC\'s Axeda\xa0agent and desktop server, which are no longer used in BD\'s products."Prior to August 2019, select BD diagnostic and biosciences products, including older versions of BD Assurity Linc, were offered with Axeda Agent and/or Axeda Desktop Server.\xa0BD is proactively reaching out to customers who may still have Axeda Agent or Axeda Desktop Server in limited instances to assist in removing the application," the medtech said, noting that it has not received any reports of the vulnerabilities being exploited on its products.However, BD last month disclosed cybersecurity vulnerabilities in its Viper and Pyxis\xa0products that allow for the use of hard-coded credentials. BD voluntarily reported the vulnerabilities to CISA and the FDA.CISA last week issued two separate advisories warning that successful exploitation of BD\'s Viper hard-coded credential vulnerability "could allow an attacker to access, modify, or delete sensitive information," while the company\'s Pyxis hard-coded credential vulnerability "could allow an attacker to gain access to electronic protected health information (ePHI) or other sensitive information."'},

{'identifier': 'https://www.medtechdive.com/topic/medical-devices/',

'title': 'Medtronic, Nevro boosted by expansion of Medicare coverage for diabetic pain devices',

'url': 'https://www.medtechdive.com/news/medtronic-nevro-boosted-by-expansion-of-medicare-coverage-for-diabetic-pai/620076/',

'date': '09-03-2022',

'keywords': 'device',

'content': 'Noridian\'s update adds two new ICD-10 codes for PDN to a pair of documents, A57791 and A57792, that address the use of SCS in chronic pain. The Medicare Administrative Contractor (MAC) covers Medicare patients in Alaska, Arizona, California, Hawaii, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington and Wyoming. Nevro said the Noridian update covers around 8% of PDN patients in the U.S.Working to capture what management sees as an "important driver"\xa0of long-term growth, Nevro needs to grow coverage of SCS in PDN to kickstart its business. The addition of Noridian coverage, which applies retroactively to procedures performed since the start of the year, keeps Nevro on track to meet analyst expectations.\xa0“The announcement is consistent with our expectation that PDN coverage expansion would be forthcoming in 2022 and beyond. For reference, we model FY22 and FY23 PDN revenue of $28.5M & $53M, respectively, and view these as achievable estimates,"\xa0analysts at Truist Securities wrote in a note to investors.Truist modeled $23 million and $38 million in PDN sales for 2022 and 2023, respectively, at the time of the UnitedHealthcare coverage decision. Since then, Medtronic has won approval ahead of schedule. The Truist analysts said the presence of Medtronic "will help develop the referral channel"\xa0but could also "strip away near-term ... upside optionality"\xa0for Nevro.The arrival of Medtronic in the market means expanding coverage benefits both Nevro and its rival. At the time of the Medtronic approval, analysts said Nevro management "wants to rectify"\xa0the fact that the UnitedHealthcare coverage is not specific to their device. Yet, as it stands, neither UnitedHealthcare nor Noridian has differentiated between the Nevro and Medtronic devices in their coverage."Noridian\'s update is not exclusive to any one waveform or frequency but rather based on the overall body of evidence which supports SCS as a treatment option for these patients,"\xa0a Medtronic spokesperson said in an emailed statement. "We will continue to engage with outstanding Medicare contractors and private payers to share existing clinical evidence to encourage the addition of diabetic peripheral neuropathy to their coverage policies where needed,"\xa0Nevro put a positive spin on Medtronic\'s FDA approval, with CEO Keith Grossman using a conference call to discuss fourth quarter results to argue\xa0"having a second market participant raising awareness about this indication with referring doctors and patients can only be helpful in developing the referral channel and in accelerating market expansion."\xa0Grossman made the case that Nevro has the stronger data.The challenge for Nevro now is to translate its claimed advantages into sales growth. Work to grow sales in PDN from the $4 million generated in the fourth quarter should benefit from further SCS coverage decisions.\xa0"We expect to have announcements like this throughout the year as we continue our activities to expand payer outreach to include spinal cord stimulation coverage for peripheral diabetic neuropathy,"\xa0a spokesperson for Nevro said. "We will provide updates on those payer decisions as they arise and expect our payer coverage to increase gradually over time with a steady increase in positive coverage decisions occurring throughout the year."\xa0'}],

[{'identifier': 'https://www.raps.org/news-and-articles/news-articles',

'title': 'shuren apologizes for mdufa delay, says fda will start closing the spigot on new euas',

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'content': '\n The head of the US Food and Drug Administration’s (FDA) device center was criticized by top House lawmakers for not getting a Medical Device User Fee Amendments (MDUFA V) deal to them for review on time. He apologized for missing the statutory deadline and noted his staff have been slammed due to the COVID-19 pandemic.\r\n\xa0\r\nOn 30 March, the House Energy and Commerce (E&C) subcommittee on health met to discuss renewing FDA’s MDUFA program. At the start of the meeting committee Chair Frank Pallone (D-NJ) and Ranking Member Cathy McMorris Rodgers (R-OR), scolded Jeff Shuren, director of the Center for Devices and Radiological Health (CDRH), for missing the 15 January deadline to submit a MDUFA V commitment letter. (RELATED: MDUFA V: Commitment letter includes TPLC pilot, claw back provisions and more, Regulatory Focus 23 March 2022)\r\n\xa0\r\nThe letter is a tentative deal between FDA and the medtech industry on how much revenue the agency will bring in over the next five years to help pay for reviewing premarket applications while also setting performance goals for reviewers to meet.\r\n\xa0\r\n“This deadline is not a mere suggestion it\'s actually the law and the process is important because it allows for the FDA, industry and members of the public to examine what has worked well, and where review programs can be improved through the reauthorization process,” said Pallone. “It also provides Congress with time to thoroughly review these recommendations and reauthorize the program ahead of the funding deadline.”\r\n\xa0\r\nPallone noted that FDA and industry were not only delayed two months but since they only got the letter a week ago there hasn’t been enough time for the agency to collect public comments on the deal which he argued has serious unanswered questions on a number of issues. Despite the delay, he said Congress will get the program reauthorized before it expires on 30 September, so that FDA isn’t forced to lay off staff paid through the device user fee program.\r\n\xa0\r\n“I\'m not trying to beat you up Dr. Shuren but the bottom line is we get this two months later, we\'re going to meet our deadline because we don\'t want to have the pink slips but I remember a few years ago when the pink slips went out and everybody was saying, \'Well Congress why didn\'t you do this quicker?\'” Pallone said. “Well in this case it\'s your fault. I don\'t know how else to put it.”\r\n\xa0\r\nMcMorris Rodgers, also piled on and expressed her disappointment with FDA and industry for missing the deadline and only giving lawmakers a week to review the deal. She also noted that she’s concerned about “the lack of transparency” throughout the MDUFA negotiation process and wrote to then acting FDA Commissioner Janet Woodcock about the agency’s delay in posting meeting minutes.\r\n\xa0\r\n"To ensure transparency and progress, documentation of meeting outcomes and action items are supposed to be made part of the official record and made publicly available,” she said. “While posting minutes publicly takes no more than two to three weeks, during MDUFA V negotiations we saw delays of 6 months. Even today there are no meeting minutes posted for any meetings that took place after June 30, 2021."\r\n\xa0\r\nIn response to the criticism, Shuren apologized to lawmakers for the delay and noted that his staff have had to put a lot of things on the backburner to prioritize their work on developing guidances and reviewing emergency use authorization (EUA) applications related to the pandemic.\r\n\xa0\r\n"I want you to know I personally regret that we missed the statutory deadline to deliver our recommendations to congress. I and the entire agency take this obligation very seriously,” he said. “I am pleased to report however that the long deliberations have ultimately produced a strong thoughtful agreement on recommendations to congress that if enacted will continue to advance medical device innovation while maintaining the FDA’s standards to protect patients."\r\n\xa0\r\nShuren noted that while the agency met or exceeded its MDUFA obligations at the start of the pandemic, it eventually was overwhelmed and ended up falling short on a number of metrics due to increase in workload for which the agency wasn’t well-funded. He also added that its reviewers received 15 times the number of EUAs that they typically see during a public health emergency (PHE) and overall received 8,000 EUAs of which they’ve authorized 2,200. They are reportedly still receiving about 130 EUA applications a month.\r\n\xa0\r\n"This has been a perfect storm my center has been battling for two years… with many of my staff burning the midnight oil and burning out in the process," said Shuren.\r\n\xa0\r\nIf Congress fails to reauthorize the MDUFA deal by September, Shuren warned that FDA will have to start laying off staff which could lead to delays in product reviews and the US risks losing its edge in getting medical technologies to market first.\r\n\xa0\r\nPallone asked Shuren, what could be done to make the MDUFA negotiation deal better so that the same kind of delay is avoided in another five years when MDUFA VI is being negotiated.\r\n\xa0\r\nShuren again noted that this was an unusual situation because FDA was delayed due to the pandemic but suggested adding an additional deadline.\r\n\xa0\r\n“This was us and industry saying we\'re getting hammered with COVID, we need more time,” he said. “One thing maybe congress can do is rather than just have the date when you have to come to congress, have the date when we have to sit down and get this started so we have enough lead time to get it done."\r\n\xa0\r\nMcMorris Rodgers pushed on the fact FDA hasn’t provided meeting minutes on negotiations between itself and industry since 30 June and asked Shuren how many meetings have been held since. She noted that the lack of minutes means lawmakers and the public has been left without much context on how the MDUFA deal was developed.\r\n\xa0\r\nPast reporting has indicated that FDA and industry also suddenly halted public negotiations in late November and then went into overdrive after the 15 January deadline to finally come to an agreement. McMorris Rodgers pressed Shuren on how many meetings were held between FDA and industry in that timeframe.\r\n\xa0\r\nShuren noted that while the meeting minutes have not been posted, he estimates FDA and industry met over a dozen times since 30 June to hash out a deal. He explained that MDUFA negotiations are very sensitive like international treaties with a lot of parties involved and all sides were more focused on reaching a deal.\r\n\xa0\r\n"We put the priority on getting the deal done than the meeting minutes," he said.\r\n\xa0\r\nShuren also noted that while there weren’t a lot of in-person meetings between December and January, there were a lot of offline discussions with industry to get to a deal.\r\n\xa0\r\nRep. Anna Eshoo (D-CA), chair of the health subcommittee, asked Shuren what FDA’s plan is over the long term to help alleviate the extra burdens caused by the agency’s response to EUAs.\r\n\xa0\r\nShuren said the agency is taking steps to narrow their focus to EUA devices that are especially important in the pandemic fight.\r\n\xa0\r\n"Over the coming months the goal really is to start turning off the spigot on EUAs [because] there\'s enough product out there," he said.\r\n\xa0\r\nDuring the hearing McMorris Rodgers noted that FDA published two draft guidances in December on transitioning EUA products to regular marketing authorization. In response, industry groups have raised concerns that the agency’s proposed guidances don’t give companies enough time to submit a premarket application and make labeling changes. https://www.raps.org/news-and-articles/news-articles/2022/3/stakeholders-ask-for-more-time-to-transition-eua-d\r\n\xa0\r\nShe asked whether FDA was taking those concerns into account so as not to worsen potential supply chain shortages that could affect patient access to devices, and whether it had the resources needed to handle the influx of applications.\r\n\xa0\r\nShuren said that FDA is still reviewing the comments but encouraged manufacturers to not wait for the PHE to be over to transition their products to regular marketing status. He said if device makers know they plan to make that transition they should come to FDA as soon as possible with their data and start the process.\r\n\xa0\r\n“Also remember the product is already on the market and we\'re going to focus on new product applications but we\'re not going to disenfranchise anyone who already has their product on the market,” he added.\r\n\xa0\r\nA major concern that Shuren and other FDA leadership have raised during the pandemic is they are worried that experienced staff are burning out from their pandemic workload and potentially leaving the agency. The director noted that work flexibility such as being allowed to work from home has helped the agency keep staff and they are seeing better recruitment than ever before. However, one thing he said that could be very helpful in recruiting more people is if Congress gave FDA direct hiring authority that isn’t tied to certain legislation such as the 21st Century Cures Act.\r\n\xa0\r\n"If we find the right person, let\'s bring them in as quickly as possible," said Shuren.\r\n\xa0\r\nMaybe the most contentious issue between FDA and industry during the MDUFA V negotiations was the agency’s wish to create a total product lifecycle advisory program (TAP) that could incorporate external stakeholders such as physicians and insurance providers during the presubmission process. While industry pushed back on the issue stating it didn’t think there was a lot of interest from external stakeholders to participate in the program, FDA argued it could help manufacturers better understand what users and insurers want to see in a product to better inform its development. Ultimately, the two sides agreed to start off with a TAP pilot program to see if it is successful.\r\n\xa0\r\nRep. Brett Guthrie (R-KY) asked Shuren what the difference was between the TAP program and FDA’s presubmission program that allows product sponsors to discuss product development before submitting their device for agency review.\r\n\xa0\r\nShuren noted that while the presubmission program was immensely popular with sponsors, it’s narrowly structured to address individual questions in a back-and-forth process that can be relatively slow. The TAP program on the other hand according to the director address bigger marketing questions close to real-time.\r\n\xa0\r\nHe said it also addresses a major issue that the medtech industry has long complained about called the “valley of death,” which is the time between when a product gets FDA marketing authorization and when it starts getting reimbursed by insurers based on factors such as clinical meaningfulness.\r\n\xa0\r\n"If we can solve the challenges before we get the submission, we\'re not talking about saving days, we\'re talking about saving months and years in getting to yes more efficiently,” said Shuren. “TAP can be a gamechanger, and this is what we learned from COVID that it really works, it\'s part of the secret sauce, that got those 2,200 devices out onto the market."\r\n\xa0\r\nWhen asked about the fact MDUFA V potentially almost doubles its expected revenue compared to MDUFA IV, Shuren stated that the previous user fee deal was under-resourced, and the agency had no way to adjust it.\r\n\xa0\r\nBy contrast, he added the MDUFA V deal is designed to deal with resource gaps while also allowing the agency to improve its performance goals which includes the TAP pilot program, more funding for analyzing real-world evidence, adopting national and international consensus standards and driving international harmonization, which Shuren characterized as the “next frontier.”\r\n\xa0\r\nOn a separate matter, Eshoo also noted that in June 2021, FDA published a draft guidance that attempts to clarify the different between servicing and remanufacturing. She asked whether the agency needs further clarification of the terms in statute which presumably could be added as an amendment when the reauthorization bill is passed. (RELATED: FDA explains when device \'servicing\' becomes \'remanufacturing\', Regulatory Focus 17 June 2021)\r\n\xa0\r\nShuren said that FDA is still looking over the comments but "there is value in providing greater clarity and maybe even doing so through statute.”\r\n\xa0\r\n“When we saw reports come in with servicing [adverse events] most of those had to do with remanufacturing, so clarity about what constitutes and what doesn\'t constitute remanufacturing is important,” he added.\r\n\xa0\nHearing\n'},

{'identifier': 'https://www.raps.org/news-and-articles/news-articles',

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'content': "\n A weekly update on new drug approvals and indications from the US Food and Drug Administration (FDA).\r\n\xa0\nNew approval\nPluvicto approved for metastatic, castration-resistant prostate cancer\r\nAdvanced Accelerator Applications’ Pluvicto (lutetium [Lu 177] vipivotide tetraxetan; injection) is approved as a radioligand therapy for metastatic castration-resistant prostate cancer in men who are positive for prostate-specific membrane antigen and have been treated with an androgen receptor pathway inhibitor and taxane-based chemotherapy.\r\n\xa0\r\nLocametz (gallium Ga 68 gozetotide), a radioactive diagnostic agent, was concurrently approved for selecting patients for treating with Pluvicto.\r\n\xa0\r\nApproval of Pluvicto was based on findings from the multicenter, open label VISION trial in which patients from the indicated population were randomized 2:1 to receive Pluvicto plus best standard of care (BSoC; 551 patients) or BSoC alone (280 patients). Median overall survival in the Pluvicto group was 15.3 months, compared with 11.3 months BSoC arm. Interpretation of the magnitude of the radiographic progression-free survival effect was limited due to a high degree of censoring from early dropout in the control arm.\r\n\xa0\r\nThe review of this application used the assessment aid. The application was granted priority review and breakthrough designations.\n\nNew indications\nCabenuva HIV regimen nabs expanded indication for adolescents\r\nViiV Healthcare’s Cabenuva (cabotegravir and rilpivirine) has been granted a new indication for treating HIV-1 in virologically suppressed patients aged 12 years or older.\r\n\xa0\r\nThe long-acting regimen was codeveloped with Janssen as a once-monthly or every-two-months’ treatment. It contains ViiV's cabotegravir and Janssen’s rilpivirine, both extended release injectable suspensions.\r\n\xa0\r\nApproval for the expanded indication was supported by efficacy findings extrapolated from adults with support from pharmacokinetic analyses showing similar drug exposure and from safety data from the week 16 interim analysis of the ongoing MOCHA study in 23 patients from the indicated population.\r\n\xa0\r\nCabenuva was originally approved in 2021 for treating adults living with HIV-1.\r\n\xa0\nFintepla okayed for seizures associated with Lennox-Gastaut syndrome\r\nUCB’s Fintepla (fenfluramine; oral solution) has been granted a new indication for treating seizures associated with Lennox-Gastaut syndrome in patients aged 2 years or older.\r\n\xa0\r\nFintepla was originally approved in 2020 for the treatment of seizures associated with Dravet syndrome in the same age group. The therapy was developed by Zogenix, which was acquired by UCB in March 2022.\r\n\xa0\r\nApproval of Fintepla was based on findings from a Phase 3 global, placebo-controlled clinical trial in 263 patients from the indicated population. Monthly seizure frequency dropped by a median 23.7% from baseline in patients receiving Fintepla, compared with 8.7% in those receiving placebo.\r\n\xa0\r\nFintepla comes with a warning for valvular heart disease and pulmonary arterial hypertension.\n\r\n\xa0\n "},

{'identifier': 'https://www.raps.org/news-and-articles/news-articles',

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'date': '29-03-2022',

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'content': "\n The Philippine Food and Drug Administration (FDA) is seeking feedback on the expedited review of medical devices that already have been authorized by another national regulatory authority (NRA) in the Association of Southeast Asian Nations (ASEAN).\r\n\xa0\r\nIn line with World Health Organization advice about the benefits of relying on other regulatory agencies, FDA has set out draft guidelines on the abridged processing of fillings for registration and notification of certain medical devices. The expedited pathway will apply to products approved by the NRA of an ASEAN member country under the requirements of the ASEAN Medical Device Directive Common Submission Dossier Template (AMDD-CSDT).\r\n\xa0\r\n“The applicant shall submit complete legal and applicable technical requirements when applying for registration/notification of medical devices. The technical requirements to be submitted shall be the same as those submitted to the reference NRA of the ASEAN member country where the Certificate of Product Registration (CPR) was issued,” the guidelines state.\r\n\xa0\r\nFDA is proposing that applicants attest that the CSDT technical documentation is identical to that filed with the other ASEAN NRA and acknowledge that the agency may automatically suspend the product if there is an unauthorized change in its details and documentation. Unauthorized changes also may trigger voluntary recalls. FDA is indemnified against third-party claims relating to unauthorized changes under the draft guidenlines.\r\n\xa0\r\nSubmissions for expedited review will undergo a pre-assessment process, during which FDA will check the completeness of the legal and technical requirements. FDA will only issue an order of payment after determining that an application is complete. The agency will verify the submitted CPR from the reference NRA of the ASEAN member country.\r\n\xa0\r\nCPRs issued based on an abridged approval in countries outside the ASEAN are ineligible, and the pathway is only open to Class B, C and D medical devices. FDA is reserving the right to refuse expedited review if it receives a negative report about the medical device from other countries, ASEAN NRAs have conflicting views about a product or because it otherwise thinks a full evaluation is needed.\r\n\xa0\r\nFDA is accepting feedback on the proposal until 25 April.\r\n\xa0\nDraft Guidelines\r\n\xa0\nTGA fines COVID vaccine developer for alleged unlawful advertising\r\n\xa0\r\nAustralia’s Therapeutic Goods Administration (TGA) has fined Vaxine AU$13,320 ($9,970) for allegedly unlawful advertising an unapproved COVID-19 vaccine. The allegation centers on content published on Facebook and YouTube.\r\n\xa0\r\nVaxine has raised AU$1 million through a crowdfunding campaign to push for approval of its recombinant protein COVID-19 vaccine candidate, Advax-CpG55.2, in its home market of Australia. TGA granted Vaxine provisional determination late last year, clearing it to apply for provisional registration in the Australian Register of Therapeutic Goods.\r\n\xa0\r\nTGA issued Vaxine with an infringement notice because the company “did not adequately address a range of concerns with the social media advertisement” that the agency raised with the company’s director by phone and in writing.\r\n\xa0\r\nTGA said that, while factual information about clinical trials is published on Australian New Zealand Clinical Trials Registry and related overseas registries, sponsors cannot advertise unapproved goods such as candidates undergoing clinical trials because they are yet to complete assessment by the agency.\r\n\xa0\r\n“Publicly available information about any clinical trial must be factual and balanced and must not promote the use or supply of the therapeutic goods that are the subject of the trial. Advertisers of therapeutic goods are reminded that the term 'advertise' in relation to therapeutic goods refers to any statement, pictorial representation or design that is intended to promote the use or supply of the goods in the eyes of a reasonable consumer,” TGA wrote.\r\n\xa0\nTGA Notice\r\n\xa0\nChina’s NMPA posts guidance on self-inspection of device quality systems\r\n\xa0\r\nChina’s National Medical Products Administration (NMPA) has updated its guidance on the annual self-inspection of medical device quality management systems as part of a raft of changes that will take effect on 1 May.\r\n\xa0\r\nThe updated guideline is one of three new or updated documents that NMPA will implement in a little over one month. The other documents cover prohibited medical device manufacturing and compiling quality agreements. NMPA framed the documents as a way to strengthen the supervision of medical device production and ensure the safety and effectiveness of products sold in China.\r\n\xa0\r\nThe release of the documents comes one year after China’s State Council released details of a significant revision to the medical device regulatory framework. The revised framework clarified that medical device marketing authorization holders are responsible for the safety of and effectiveness of their products throughout the life cycle.\r\n\xa0\nNMPA Notice (Chinese)\r\n\xa0\nIndia approves Novavax’s COVID vaccine for use in adolescents\r\n\xa0\r\nThe Drugs Controller General of India (DCGI) has granted emergency use authorization (EUA) to Novavax’s COVID-19 vaccine in adolescents aged 12 to 18 years. Novavax said the DCGI decision is the first authorization of its protein-based vaccine in the adolescent population.\r\n\xa0\r\nWorking with the Serum Institute of India, Novavax secured EUA for its NVX-CoV2373 vaccine in India in adults late last year. The extension of the label to cover adolescents is underpinned by a phase 2/3 clinical trial that studied the vaccine in 460 Indian individuals aged 12 to 18 years. According to Novavax, the trial showed NVX-CoV2373 “was well-tolerated with a reassuring safety profile.”\r\n\xa0\r\nThe EUA filing also referenced data from a US clinical trial that delivered topline data earlier this year. That study, which took place before the rapid rise of the Omicron variant, linked the vaccine to 82% clinical efficacy against the Delta variant.\r\n\xa0\nPress Release\r\n\xa0\nChina’s NMPA prepares for WHO assessment of vaccine regulatory capacity\r\n\xa0\r\nChina’s NMPA has held a meeting in preparation for a national regulatory authority (NRA) assessment of vaccines by the World Health Organization (WHO). The assessment will cover China’s vaccine regulatory capacity and level.\r\n\xa0\r\nVaccine regulation has been a source of headaches for China in recent years, with scandals such as the discovery that Changsheng Biotechnology had fabricated production and inspection records rocking the country. Since then, Chinese authorities have sought to improve oversight, jailing some ex-regulatory officials and taking steps to enhance quality management and traceability.\r\n\xa0\r\nThe upcoming WHO assessment in June represents a test of China’s vaccine regulatory capacity and level. NMPA wants to ensure China passess the test and lays the groundwork for future enhancements to the system.\r\n\xa0\r\n“In terms of current problems and challenges, it is important to carefully analyze causes and accelerate rectification and improvement. Efforts should be made not only to pass the assessment, but also to lay a solid foundation for the modernization of China's vaccine regulatory system and capacity in the long run,” NMPA wrote.\r\n\xa0\nNMPA Notice\r\n\xa0\nOther news:\r\n\xa0\r\nThe Philippine FDA has issued warnings against the purchase of a clutch of counterfeit products. One of the warnings covers counterfeit versions of Alaxan, a combination of ibuprofen and paracetamol. The other warning presents details of counterfeit versions of Dolfenal, Solmux and Tuseran Forte. The FDA warnings are aimed at healthcare professionals, consumers and retailers of medicines. FDA Notice, More\n"}]]

In [4]:

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# Adding a simple pipeline component to allow custom sentence boundary detection,

# logic that doesn't require the dependency parse.

nlp.add\_pipe('sentencizer')

Out[4]:

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In [5]:

df = pd.DataFrame()

# Data Cleaning

for all\_news in dataHuggingFace:

if len(all\_news) >= 1:

df1 = pd.DataFrame(all\_news)

df = pd.concat([df, df1])

df = df.reset\_index(drop = True)

nan\_value = float("NaN")

df.replace("", nan\_value, inplace=True)

df.dropna(subset = ["content"], inplace=True)

df

Out[5]:

|  | keywords | identifier | title | url | date | content |
| --- | --- | --- | --- | --- | --- | --- |
| 0 | medical devices | device | https://www.mddionline.com/regulatory-quality/... | tactics for developing connected medical devices | https://www.mddionline.com/digital-health/tact... | 30-03-2022 | Collaboration across medical device developmen... |
| 1 | device | https://www.mddionline.com/regulatory-quality/... | cloudcath wins fda nod for connected device th... | https://www.mddionline.com/digital-health/clou... | 30-03-2022 | Patients with end-stage renal disease (ESRD) w... |
| 2 | 510(k) | https://www.fdanews.com/articles/topic/106?page=5 | Orthofix Receives FDA’s 510(k) Clearance for i... | https://www.fdanews.com/articles/207065-orthof... | 22-03-2022 | Orthofix Medical has been granted the FDA’s 51... |
| 3 | advamed | https://www.fdanews.com/articles/topic/106?page=5 | AdvaMed Says COVID-19 Test Manufacturing Must ... | https://www.fdanews.com/articles/207064-advame... | 22-03-2022 | The device trade association AdvaMed has issue... |
| 4 | 510(k) | https://www.fdanews.com/articles/topic/106?page=5 | BioMérieux Gets FDA’s 510(k) Clearance for its... | https://www.fdanews.com/articles/207063-biom%C... | 22-03-2022 | In vitro diagnostics company bioMérieux’s Vite... |
| 5 | device | https://www.fdanews.com/articles/topic/106?page=5 | Enteral Device Industry Phasing Out ‘Legacy’ E... | https://www.fdanews.com/articles/207044-entera... | 21-03-2022 | Manufacturers of enteral devices are phasing o... |
| 6 | recall | https://www.fdanews.com/articles/topic/106?page=5 | FDA Provides Update on Celltrion’s Recall of S... | https://www.fdanews.com/articles/207041-fda-pr... | 21-03-2022 | The FDA has issued on update on Celltrion’s Fe... |
| 7 | notified body | https://www.medtechdive.com/topic/medical-devi... | Notified body update dampens hopes of near-ter... | https://www.medtechdive.com/news/notified-body... | 30-03-2022 | The European Commission provided an update on ... |
| 8 | device | https://www.medtechdive.com/topic/medical-devi... | FDA asks Congress for 14% bump in device budge... | https://www.medtechdive.com/news/fda-congress-... | 29-03-2022 | The FDA is requesting an overall budget of $8.... |
| 9 | device | https://www.medtechdive.com/topic/medical-devi... | MDR updates safety, clinical performance requi... | https://www.medtechdive.com/news/mdr-safety-pe... | 28-03-2022 | MDCG, which advises the European Commission on... |
| 10 | mdufa | https://www.medtechdive.com/topic/medical-devi... | FDA sets terms for MDUFA V agreement | https://www.medtechdive.com/news/fda-mdufa-v-a... | 23-03-2022 | Industry groups largely supported MDUFA V, tho... |
| 11 | recall | https://www.medtechdive.com/topic/medical-devi... | Another Philips ventilator recall gets Class I... | https://www.medtechdive.com/news/another-phili... | 23-03-2022 | The quality standards of Philips' respiratory ... |
| 12 | recall | https://www.medtechdive.com/topic/medical-devi... | FDA labels Philips 2018 field correction for v... | https://www.medtechdive.com/news/fda-labels-ph... | 22-03-2022 | In June, Philips initiated a recall of sleep a... |
| 13 | designation | https://www.medtechdive.com/topic/medical-devi... | Dexcom's hospital glucose monitor leads latest... | https://www.medtechdive.com/news/dexcom-breakt... | 22-03-2022 | Dexcom has led the latest batch of FDA breakth... |
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| 17 | device | https://www.medtechdive.com/topic/medical-devi... | Steep drop in medical device reports on Bayer'... | https://www.medtechdive.com/news/drop-in-devic... | 15-03-2022 | Bayer stopped selling Essure, an implant desig... |
| 18 | device | https://www.medtechdive.com/topic/medical-devi... | Apyx's surgical device gets FDA warning on off... | https://www.medtechdive.com/news/apyxs-surgica... | 15-03-2022 | Dermal resurfacing is a long-standing target m... |
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| 21 | device | software | https://www.medtechdive.com/topic/medical-devi... | FDA warns of cyber vulnerabilities in medical ... | https://www.medtechdive.com/news/fda-cyber-vul... | 09-03-2022 | All versions of PTC's Axeda agent and desktop ... |
| 22 | device | https://www.medtechdive.com/topic/medical-devi... | Medtronic, Nevro boosted by expansion of Medic... | https://www.medtechdive.com/news/medtronic-nev... | 09-03-2022 | Noridian's update adds two new ICD-10 codes fo... |
| 23 | mdufa | https://www.raps.org/news-and-articles/news-ar... | shuren apologizes for mdufa delay, says fda wi... | https://www.raps.org/news-and-articles/news-ar... | 30-03-2022 | \n The head of the US Food and Drug Admin... |
| 24 | approval | https://www.raps.org/news-and-articles/news-ar... | fda approvals roundup: pluvicto, cabenuva, fin... | https://www.raps.org/news-and-articles/news-ar... | 30-03-2022 | \n A weekly update on new drug approvals ... |
| 25 | medical devices | device | https://www.raps.org/news-and-articles/news-ar... | asia-pacific roundup: philippine fda seeks fee... | https://www.raps.org/news-and-articles/news-ar... | 29-03-2022 | \n The Philippine Food and Drug Administr... |

In [6]:

# Using regular expression for data cleaning

import re

for i in range(len(df['content'])):

text = df['content'][i]

df['content'][i] = re.sub(r'\s+', ' ', text)

df

Out[6]:

|  | keywords | identifier | title | url | date | content |
| --- | --- | --- | --- | --- | --- | --- |
| 0 | medical devices | device | https://www.mddionline.com/regulatory-quality/... | tactics for developing connected medical devices | https://www.mddionline.com/digital-health/tact... | 30-03-2022 | Collaboration across medical device developmen... |
| 1 | device | https://www.mddionline.com/regulatory-quality/... | cloudcath wins fda nod for connected device th... | https://www.mddionline.com/digital-health/clou... | 30-03-2022 | Patients with end-stage renal disease (ESRD) w... |
| 2 | 510(k) | https://www.fdanews.com/articles/topic/106?page=5 | Orthofix Receives FDA’s 510(k) Clearance for i... | https://www.fdanews.com/articles/207065-orthof... | 22-03-2022 | Orthofix Medical has been granted the FDA’s 51... |
| 3 | advamed | https://www.fdanews.com/articles/topic/106?page=5 | AdvaMed Says COVID-19 Test Manufacturing Must ... | https://www.fdanews.com/articles/207064-advame... | 22-03-2022 | The device trade association AdvaMed has issue... |
| 4 | 510(k) | https://www.fdanews.com/articles/topic/106?page=5 | BioMérieux Gets FDA’s 510(k) Clearance for its... | https://www.fdanews.com/articles/207063-biom%C... | 22-03-2022 | In vitro diagnostics company bioMérieux’s Vite... |
| 5 | device | https://www.fdanews.com/articles/topic/106?page=5 | Enteral Device Industry Phasing Out ‘Legacy’ E... | https://www.fdanews.com/articles/207044-entera... | 21-03-2022 | Manufacturers of enteral devices are phasing o... |
| 6 | recall | https://www.fdanews.com/articles/topic/106?page=5 | FDA Provides Update on Celltrion’s Recall of S... | https://www.fdanews.com/articles/207041-fda-pr... | 21-03-2022 | The FDA has issued on update on Celltrion’s Fe... |
| 7 | notified body | https://www.medtechdive.com/topic/medical-devi... | Notified body update dampens hopes of near-ter... | https://www.medtechdive.com/news/notified-body... | 30-03-2022 | The European Commission provided an update on ... |
| 8 | device | https://www.medtechdive.com/topic/medical-devi... | FDA asks Congress for 14% bump in device budge... | https://www.medtechdive.com/news/fda-congress-... | 29-03-2022 | The FDA is requesting an overall budget of $8.... |
| 9 | device | https://www.medtechdive.com/topic/medical-devi... | MDR updates safety, clinical performance requi... | https://www.medtechdive.com/news/mdr-safety-pe... | 28-03-2022 | MDCG, which advises the European Commission on... |
| 10 | mdufa | https://www.medtechdive.com/topic/medical-devi... | FDA sets terms for MDUFA V agreement | https://www.medtechdive.com/news/fda-mdufa-v-a... | 23-03-2022 | Industry groups largely supported MDUFA V, tho... |
| 11 | recall | https://www.medtechdive.com/topic/medical-devi... | Another Philips ventilator recall gets Class I... | https://www.medtechdive.com/news/another-phili... | 23-03-2022 | The quality standards of Philips' respiratory ... |
| 12 | recall | https://www.medtechdive.com/topic/medical-devi... | FDA labels Philips 2018 field correction for v... | https://www.medtechdive.com/news/fda-labels-ph... | 22-03-2022 | In June, Philips initiated a recall of sleep a... |
| 13 | designation | https://www.medtechdive.com/topic/medical-devi... | Dexcom's hospital glucose monitor leads latest... | https://www.medtechdive.com/news/dexcom-breakt... | 22-03-2022 | Dexcom has led the latest batch of FDA breakth... |
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| 17 | device | https://www.medtechdive.com/topic/medical-devi... | Steep drop in medical device reports on Bayer'... | https://www.medtechdive.com/news/drop-in-devic... | 15-03-2022 | Bayer stopped selling Essure, an implant desig... |
| 18 | device | https://www.medtechdive.com/topic/medical-devi... | Apyx's surgical device gets FDA warning on off... | https://www.medtechdive.com/news/apyxs-surgica... | 15-03-2022 | Dermal resurfacing is a long-standing target m... |
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| 20 | mdufa | https://www.medtechdive.com/topic/medical-devi... | FDA reaches MDUFA V agreement with industry | https://www.medtechdive.com/news/fda-reaches-m... | 09-03-2022 | The road to hammering out a MDUFA V agreement ... |
| 21 | device | software | https://www.medtechdive.com/topic/medical-devi... | FDA warns of cyber vulnerabilities in medical ... | https://www.medtechdive.com/news/fda-cyber-vul... | 09-03-2022 | All versions of PTC's Axeda agent and desktop ... |
| 22 | device | https://www.medtechdive.com/topic/medical-devi... | Medtronic, Nevro boosted by expansion of Medic... | https://www.medtechdive.com/news/medtronic-nev... | 09-03-2022 | Noridian's update adds two new ICD-10 codes fo... |
| 23 | mdufa | https://www.raps.org/news-and-articles/news-ar... | shuren apologizes for mdufa delay, says fda wi... | https://www.raps.org/news-and-articles/news-ar... | 30-03-2022 | The head of the US Food and Drug Administrati... |
| 24 | approval | https://www.raps.org/news-and-articles/news-ar... | fda approvals roundup: pluvicto, cabenuva, fin... | https://www.raps.org/news-and-articles/news-ar... | 30-03-2022 | A weekly update on new drug approvals and ind... |
| 25 | medical devices | device | https://www.raps.org/news-and-articles/news-ar... | asia-pacific roundup: philippine fda seeks fee... | https://www.raps.org/news-and-articles/news-ar... | 29-03-2022 | The Philippine Food and Drug Administration (... |

In [7]:

LongSummary = []

ShortSummary = []

for text\_corpus in df['content']:

doc = nlp(text\_corpus.replace("\n", ""))

sentences = [sent.text.strip() for sent in doc.sents]

# Let's create an organizer which will store the sentence ordering to later reorganize the

# scored sentences in their correct order

sentence\_organizer = {k:v for v,k in enumerate(sentences)}

# Let's now create a tf-idf (Term frequnecy Inverse Document Frequency) model

tf\_idf\_vectorizer = TfidfVectorizer(min\_df=2, max\_features=None,

strip\_accents='unicode',

analyzer='word',

token\_pattern=r'\w{1,}',

ngram\_range=(1, 3),

use\_idf=1,smooth\_idf=1,

sublinear\_tf=1,

stop\_words = 'english')

# Passing our sentences treating each as one document to TF-IDF vectorizer

tf\_idf\_vectorizer.fit(sentences)

# Transforming our sentences to TF-IDF vectors

sentence\_vectors = tf\_idf\_vectorizer.transform(sentences)

# Getting sentence scores for each sentences

sentence\_scores = np.array(sentence\_vectors.sum(axis=1)).ravel()

# Sanity checkup

print(len(sentences) == len(sentence\_scores))

# Getting top-n sentences

N = 4

summary = " "

shortSummary = " "

if len(sentences) < 4:

summary = " ".join(sentences)

shortSummary = " ".join(sentences)

else:

top\_n\_sentences = [sentences[ind] for ind in np.argsort(sentence\_scores, axis=0)[::-1][:N]]

top\_nshort\_sentences = [sentences[ind] for ind in np.argsort(sentence\_scores, axis=0)[::-1][:N-2]]

# Let's now do the sentence ordering using our prebaked sentence\_organizer

# Let's map the scored sentences with their indexes

mapped\_top\_n\_sentences = [(sentence,sentence\_organizer[sentence]) for sentence in top\_n\_sentences]

mapped\_top\_nshort\_sentences = [(sentence,sentence\_organizer[sentence]) for sentence in top\_nshort\_sentences]

print("Our top\_n\_sentence with their index: \n")

for element in mapped\_top\_n\_sentences:

print(element)

# Ordering our top-n sentences in their original ordering

mapped\_top\_n\_sentences = sorted(mapped\_top\_n\_sentences, key = lambda x: x[1])

mapped\_top\_nshort\_sentences = sorted(mapped\_top\_nshort\_sentences, key = lambda x: x[1])

ordered\_scored\_sentences = [element[0] for element in mapped\_top\_n\_sentences]

ordered\_scoredshort\_sentences = [element[0] for element in mapped\_top\_nshort\_sentences]

# Our final summary

summary = " ".join(ordered\_scored\_sentences)

shortSummary = " ".join(ordered\_scoredshort\_sentences)

LongSummary.append(summary)

ShortSummary.append(shortSummary)

df['Long-Summary'] = LongSummary

df['Short-Summary'] = ShortSummary

del df['content']

True

Our top\_n\_sentence with their index:

('Remedios will then moderate a panel discussion, Connected Device Design: Using Best Practices During the Product Development Process, shortly after in 208AB on April 12 from 10:30 – 11:15 a.m. He will be joined by panelists Tom Ulrich, Ph.D. and Chief Scientist, Tandem Diabetes Care; Jeff Gross, Chief Technology Officer, Canary Medical; and Patrick Bangert, Vice President of AI, Samsung, SDSA.', 7)

('Remedios will explore the potential of such strategies in the MD&M West conference session, "Outsprint Your Competition to Market Launch by Streamlining Your Collaboration Roadmap," held in Room 210AB April 12 from 9:30 – 10:15 a.m. “Attendees will learn how to establish stakeholder strategy alignment early on with collaboration among executive, technical, marketing, manufacturing, sales, and service teams,” Remedios said. “', 4)

('It is desirable to be an early provider of these new devices, so in order to reduce time-to-market, device companies need to move toward higher levels of concurrent collaboration among disparate development teams involved in traditional embedded design, application software, and other connected technologies.”', 2)

('Attendees of the panel discussion “will learn development best practices that maximize the stability of interoperative technologies and the regulatory landscape, including privacy and use-safety challenges associated with widely varying environmental and operating conditions.”', 10)

True

Our top\_n\_sentence with their index:

('Changes in fluid turbidity are detected by CloudCath’s proprietary cloud-based algorithm and notifications are sent to clinicians and patients to alert them to seek additional medical evaluation.”', 14)

('Dialysis Monitoring to Avoid Clinical Deterioration “The CloudCath device is designed to support the clinician/patient partnership for at-home PD therapy,” said Elbadry, adding, “Actually, the entire dialysis ecosystem has a current and urgent goal to maximize use of home modalities.”', 5)

('Although focused on home PD, of course, the CloudCath System can also be used in healthcare settings like longterm care facilities and, in the rare case that a patient moves to a hospital and continues PD treatment, the CloudCath System could be used in a hospital setting,” said Elbadry.', 20)

('With a cloud-based digital connection, the PD monitoring system continuously provides data that can tip a physician off to a brewing health issue. “', 7)

True

True

Our top\_n\_sentence with their index:

('Among other measures, the association wants the federal government to partner with the device industry for “warm base manufacturing” arrangements.', 2)

('The device trade association AdvaMed has issued an urgent call for more federal funding to produce COVID-19 diagnostic tests because the administration announced that its efforts would have to be scaled back unless Congress appropriates more money.', 0)

('A warm base refers to facilities that would be constructed and commissioned, ready to quickly manufacture products on demand.', 3)

('“Should we face another wave of cases, we must be prepared to meet the needs of patients and public health, and we cannot do that without firm public-private commitments in place with test manufacturers,” said AdvaMed President and CEO Scott Whitaker.', 1)

True

True

Our top\_n\_sentence with their index:

('Manufacturers of enteral devices are phasing out their production of older-style enteral connectors in North America to improve patient safety, a trade group says.', 0)

('The trade group says the industry’s switch to ENFit connectors will reduce the “risks of potentially fatal medical device misconnections and minimize unintentional disconnections.”', 2)

('The Global Enteral Device Supplier Association says its members and affiliates in the enteral feeding device market are increasingly converting to ENFit connectors that comply with the International Organization for Standardization’s ISO 80369-3 standard and they are updating their timelines for the phase-out of the older-style devices.', 1)

('And the use of one universal technology should also mitigate supply-chain interruptions for enteral small-bore connectors, the group said.', 3)

True

Our top\_n\_sentence with their index:

('The 45,500 affected products with the product code 83QKP were distributed from June 2 to Dec. 21, 2021.The FDA says that although it has not received any reports of injuries, adverse health consequences or death due to use of the affected test kits, “false-positive or false-negative results from improper use of these tests could lead to further exposure of uninfected individuals to the SARS-CoV-2 virus.', 2)

('The reason for the recall is a high number of false-positive reports and unauthorized shelf life labeling.', 1)

('The FDA has issued on update on Celltrion’s Feb. 28 recall of specific lots of its DiaTrust COVID-19 Ag rapid test, deeming it a Class 1 recall because of the risk of serious injury or death.', 0)

('The agency also noted “serious injury risks if someone who is not trained to collect a nasopharyngeal swab sample attempts to do so.”', 3)

True

Our top\_n\_sentence with their index:

('Two other notified bodies have progressed to the joint assessment team corrective action and preventive action (JAT CAPA) review stage since December, but none have made it past.', 5)

('The latest update, which covers the situation as of March 21, reveals a clutch of notified bodies has now cleared the JAT CAPA review stage, putting them a handful of steps from the end of the MDR designation process.', 15)

('The European Commission provided an update on the progress of notified body applications under the new regulations, revealing a growing pipeline of submissions that are approaching medical device designation but little hope of a near-term surge in in vitro diagnostic capacity.', 0)

("The Commission's March 21 update of the notified body pipeline reveals limited progress of the push to add more organizations capable of certifying products under the In Vitro Diagnostic Regulation.", 1)

True

Our top\_n\_sentence with their index:

("The agency's request for more budget authority from Congress is split fairly evenly between money for medical product safety and crosscutting, a term that captures work such as capacity building and inspection activities that span multiple departments.", 2)

('"The FDA is also seeking a further $26.4 million and 24 FTEs in relation to crosscutting work such as capacity building and inspection activities that span multiple departments.', 19)

('The establishment of a permanent device shortages program will help ensure U.S. patients and health care providers have access to the critical devices they need and help reduce U.S. dependence on devices from other nations by enhancing CDRH\'s capacity to enable rapid intervention to prevent and mitigate supply chain interruptions," the FDA wrote in its budget justification.', 7)

("At $31.4 million, the safety program is in line to receive slightly more money, reflecting the fact that it covers the single biggest change in FDA's medical device spending plans for fiscal 2023, namely RSCSP.", 4)

True

Our top\_n\_sentence with their index:

('In combination with the manufacturer\'s (single registration number) this will allow for the unique identification of the SSCP in EUDAMED and in EU."The updated template features "manufacturer’s reference number for the SSCP" at the top of the list of elements MDCG recommends manufacturers include in their summaries.', 5)

('The 2019 guide states the SSCP is "associated to one unique Basic UDI-DI."MDCG\'s update comes against a backdrop of continued debate about the implementation of MDR.', 8)

('MDCG\'s additional paragraph states: "The manufacturer will assign to the SSCP an identifier (reference number) that within the manufacturer\'s management system is unique to that SSCP and will remain the same for the entire lifetime of the SCP.', 4)

('MDCG also revised another section so it states the summary can be associated with one or multiple basic unique device identification - device identifiers (UDI-DIs).', 7)

True

Our top\_n\_sentence with their index:

('Jeff Shuren, director of the FDA\'s Center for Devices and Radiological Health, said in a news release that the new agreement "represents a substantial investment in the future of the agency\'s medical device program and would provide for important improvements, including new hiring targets, greater engagement with developers of innovative technologies based on lessons learned from the pandemic, broadened international harmonization efforts and expanded opportunities to ensure patient perspectives are an integral part of medical device development.', 10)

('The agreement will help get the FDA back on track after several years of grappling with the COVID pandemic and introduces new accountability measures related to hiring targets, accrual and use of carryover balance.', 3)

('For premarket approval submissions received in 2023 and 2024, the FDA has set a goal of 290 days to reach a decision.', 13)

('For 510(k) submissions, the FDA has set a goal of 128 days for 2023, shortening to 112 days starting in 2025.', 15)

True

Our top\_n\_sentence with their index:

('A separate recall of V60 ventilators started weeks later in response to the discovery the devices may provide the patient with a lower oxygen flow rate.', 1)

("The quality standards of Philips' respiratory business have been in the spotlight since the company began recalling millions of sleep apnea devices and ventilators over concerns the sound abatement foam may break down and expose patients to toxic chemicals.", 0)

('News of the recall comes months after Philips expanded its program to repair and replace devices that use the potentially harmful sound abatement foam.', 14)

('Philips began the latest recall of V60 ventilators in January.', 3)

True

Our top\_n\_sentence with their index:

('In the FDA\'s facility inspection form, called a Form 483, the agency wrote that the company did not notify the agency despite having reports of foam breaking down in Trilogy and other machines as early as 2014.The field correction was initiated in response to several complaints and at least one failure from a Trilogy machine caused by foam degradation, and the foam was later found to be "mutagenic, cytotoxic, carcinogenic, and non-biocompatible.', 4)

("The FDA's most recent action is now labeling the 2018 corrective action from Philips a Class I recall; the agency created an entry in its recall database on March 18.The agency discovered the corrective action during a recent facility inspection following the June recall.", 3)

('In June, Philips initiated a recall of sleep apnea and ventilator machines due to safety risks associated with polyester-based polyurethane (PE-PUR) foam used to dampen the sound of the devices.', 0)

('"According to the March 18 database entry, the Class I recall impacts Trilogy 100/200, Garbin Plus, Aeris and LifeVent Continuous Ventilators machines.', 8)

True

Our top\_n\_sentence with their index:

("After the start of the COVID-19 pandemic, the FDA issued guidance allowing glucose monitors indicated for home use to be used in a hospital setting, letting patients track and report their own blood glucose levels to reduce health care workers' exposure to the virus.", 1)

("Insightec disclosed the breakthrough designation alongside news that FDA has granted its request to trial the device in combination with Merck's checkpoint inhibitor Keytruda in NSCLC that has metastasized to the brain, and to enhance the efficacy of liquid biopsy for recurrence monitoring of patients with primary brain cancer.", 12)

('Dexcom has led the latest batch of FDA breakthrough device designations, securing the regulatory privileges for a version of its continuous glucose monitor technology designed for use in hospital settings.', 0)

("AltPep received breakthrough status for a blood test to detect Alzheimer's disease.", 17)

True

Our top\_n\_sentence with their index:

('MedTech Europe for some time has warned that although the new regulatory regime reached its date of application in 2021, significant challenges remain unresolved that could negatively impact the medtech sector including limited capacity among notified bodies, especially for certification of new and innovative devices.', 11)

('The French and German trade groups made the case that despite the MDR going into effect last year, key parts of the necessary infrastructure are still not fully operational, creating challenges in particular for small- and medium-sized medtech companies that are reaching the limits of what is feasible when it comes to the certification of new and existing devices.', 0)

('This is especially true for many small and medium enterprises, who contribute a significant portion of Europe\'s medical device innovations," MedTech Europe said in May 2021 when MDR went in effect.', 13)

('To address the backlog in the certification of existing products, BVMed and Snitem want to see the designation period for notified bodies shortened, ongoing assessments streamlined and incentives set for further applications.', 9)

True

Our top\_n\_sentence with their index:

('Last Thursday, the FDA released an order directing Philips to notify all of its customers regarding the recall of sleep apnea and ventilator machines, after the agency determined the company had failed to adequately communicate the recall and the health risks facing patients if affected devices were still used.', 0)

('In a six-page letter to Philips, the FDA said that the order comes due to "the significant period of time that has transpired since the initiation of the recall, and Philips\' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons … who should be notified, of the recall and the health risks presented by the Recalled Products.', 2)

('Along with patients and customers not being aware of the recall, the FDA wrote in its letter to the company that "it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products.', 17)

('Philips initiated a recall in June due to health risks associated with the use of certain sleep apnea and ventilator machines.', 8)

True

Our top\_n\_sentence with their index:

('There is still room to improve for FDA, particularly with 33% of respondents viewing its digital product pathway as predictable, but there was broad support for some of its key initiatives and a perception that it now offers a clearer path to market than the EU.In the survey, 79% of respondents strongly agreed or somewhat agreed that the FDA is responding effectively to advancements in medical technology.', 11)

('In its most recent assessment, FDA found almost two-third of manufacturers of novel technology devices plan to bring their products to the U.S. first or in parallel with other major markets.', 3)

('At the same time, FDA has set the target of making the U.S. the priority market for developers of novel devices.', 2)

('Only 22% of respondents said the EU pathway for regulatory approval of standard medical technology is predictable.', 9)

True

Our top\_n\_sentence with their index:

('The webpage now features details of the agency’s analysis of the medical device reports it received in relation to Essure last year.', 4)

('The company has been the main source of Essure reports to FDA since 2016.FDA said the "nature and severity of the reports in 2021 remain consistent with prior years."', 8)

('While it is now years since Essure was sold in the U.S., the analysis of data on the safety of the device continues apace.', 2)

('Bayer submitted 98% of the Essure reports received by the agency last year.', 7)

True

Our top\_n\_sentence with their index:

('In response, the FDA has told healthcare providers the device is not cleared or approved for any aesthetic skin procedures and off-label use in that context may result in serious and potentially life-threatening adverse events. "', 6)

('The reports to the agency describe "serious and potentially life-threatening adverse events after the device was used for aesthetic skin procedures."', 4)

('The number of subdermal coagulation procedures performed with the Apyx products more than doubled from 2020 to 2021.The CEO added that Apyx\'s two pending 510(k) premarket notifications remain under review by the FDA, which "are intended to obtain a general indication for use of the Renuvion Dermal handpiece in dermatological procedures requiring ablation and resurfacing of the skin, and a specific clinical indication for treating wrinkles and rhytids."', 17)

('Do not use the Renuvion/J-Plasma device for dermal resurfacing or skin contraction, alone or in combination with liposuction," the agency warned healthcare providers. "', 7)

True

Our top\_n\_sentence with their index:

('The financial impact of the recall may grow as Philips faces lawsuits in and outside of the U.S.In its annual report released in February, Philips said that the company faced about 100 class-action lawsuits in the U.S. as of Dec. 31, 2021, that allege "economic loss and/or medical monitoring claims."', 17)

('"The information currently available on Philips\' website is vague, and does not provide healthcare providers with the facts necessary for them to make informed decisions regarding the risks associated with the continued use of the Recalled Products for their patients," the agency stated in its letter.', 7)

('The FDA also ordered Philips to maintain "prominently displayed information" on their main webpage for the recall regarding the risk of using ozone cleaners on the recalled devices, which the company has attributed as one cause of the foam breakdown.', 5)

('The agency ordered Philips to notify all device users, durable medical equipment suppliers, distributors, retailers and healthcare providers that prescribe the products about the health risks posed by the foam in recalled products.', 4)

True

Our top\_n\_sentence with their index:

('In the MDUFA V agreement, TAP will be funded as a pilot with a MDUFA IV carryover balance of $110 million and an additional $45 million from base funding, according to the industry source, who noted that there will be a pilot mid-point assessment and evaluation during MDUFA VI negotiations.', 13)

('"One of the FDA\'s priorities that was ultimately included in the MDUFA V agreement was funding for the agency’s proposed total product lifecycle advisory program (TAP), which industry initially opposed.', 9)

('The MDUFA V deal, which determines how much industry pays for FDA product reviews from 2023 to 2027 and what performance goals the agency will be measured against, in the end was about compromise, according to the industry source familiar with the negotiations.', 5)

("The commitment, which CDRH made in a report on its 2022-2025 strategic priorities, comes as the center's resources continue to be strained by a COVID-19 workload and follows MDUFA V talks that exposed industry concerns about the number of vacancies at the agency.", 18)

True

Our top\_n\_sentence with their index:

("All versions of PTC's Axeda agent and desktop server are affected by the Access:7 cyber vulnerabilities, according to FDA's alert to device users and manufacturers.", 0)

('Becton Dickinson on Tuesday in a statement said it is "aware of and actively monitoring" vulnerabilities associated with PTC\'s Axeda agent and desktop server, which are no longer used in BD\'s products.', 18)

('BD voluntarily reported the vulnerabilities to CISA and the FDA.CISA last week issued two separate advisories warning that successful exploitation of BD\'s Viper hard-coded credential vulnerability "could allow an attacker to access, modify, or delete sensitive information," while the company\'s Pyxis hard-coded credential vulnerability "could allow an attacker to gain access to electronic protected health information (ePHI) or other sensitive information."', 22)

('Axel Wirth, chief security strategist of medical device cyber firm MedCrypt, called it "astounding" that nine years after CISA issued one of its early cybersecurity alerts calling out the risk of hard-coded passwords, the medtech industry is still seeing advisories that are related to hard-coded credentials.', 17)

True

Our top\_n\_sentence with their index:

('We will continue to engage with outstanding Medicare contractors and private payers to share existing clinical evidence to encourage the addition of diabetic peripheral neuropathy to their coverage policies where needed," Nevro put a positive spin on Medtronic\'s FDA approval, with CEO Keith Grossman using a conference call to discuss fourth quarter results to argue "having a second market participant raising awareness about this indication with referring doctors and patients can only be helpful in developing the referral channel and in accelerating market expansion."', 13)

('Nevro said the Noridian update covers around 8% of PDN patients in the U.S.Working to capture what management sees as an "important driver" of long-term growth, Nevro needs to grow coverage of SCS in PDN to kickstart its business.', 2)

('"Noridian\'s update is not exclusive to any one waveform or frequency but rather based on the overall body of evidence which supports SCS as a treatment option for these patients," a Medtronic spokesperson said in an emailed statement. "', 12)

('We expect to have announcements like this throughout the year as we continue our activities to expand payer outreach to include spinal cord stimulation coverage for peripheral diabetic neuropathy," a spokesperson for Nevro said. "', 17)

True

Our top\_n\_sentence with their index:

('RELATED: MDUFA V: Commitment letter includes TPLC pilot, claw back provisions and more, Regulatory Focus 23 March 2022) The letter is a tentative deal between FDA and the medtech industry on how much revenue the agency will bring in over the next five years to help pay for reviewing premarket applications while also setting performance goals for reviewers to meet. “', 4)

('At the start of the meeting committee Chair Frank Pallone (D-NJ) and Ranking Member Cathy McMorris Rodgers (R-OR), scolded Jeff Shuren, director of the Center for Devices and Radiological Health (CDRH), for missing the 15 January deadline to submit a MDUFA V commitment letter. (', 3)

('McMorris Rodgers pushed on the fact FDA hasn’t provided meeting minutes on negotiations between itself and industry since 30 June and asked Shuren how many meetings have been held since.', 31)

('During the hearing McMorris Rodgers noted that FDA published two draft guidances in December on transitioning EUA products to regular marketing authorization.', 42)

True

Our top\_n\_sentence with their index:

('New indications Cabenuva HIV regimen nabs expanded indication for adolescents ViiV Healthcare’s Cabenuva (cabotegravir and rilpivirine) has been granted a new indication for treating HIV-1 in virologically suppressed patients aged 12 years or older.', 8)

('Fintepla okayed for seizures associated with Lennox-Gastaut syndrome UCB’s Fintepla (fenfluramine; oral solution) has been granted a new indication for treating seizures associated with Lennox-Gastaut syndrome in patients aged 2 years or older.', 13)

('Approval of Pluvicto was based on findings from the multicenter, open label VISION trial in which patients from the indicated population were randomized 2:1 to receive Pluvicto plus best standard of care (BSoC; 551 patients) or BSoC alone (280 patients).', 3)

('Approval for the expanded indication was supported by efficacy findings extrapolated from adults with support from pharmacokinetic analyses showing similar drug exposure and from safety data from the week 16 interim analysis of the ongoing MOCHA study in 23 patients from the indicated population.', 11)

True

Our top\_n\_sentence with their index:

('NMPA Notice (Chinese) India approves Novavax’s COVID vaccine for use in adolescents The Drugs Controller General of India (DCGI) has granted emergency use authorization (EUA) to Novavax’s COVID-19 vaccine in adolescents aged 12 to 18 years.', 27)

('Press Release China’s NMPA prepares for WHO assessment of vaccine regulatory capacity China’s NMPA has held a meeting in preparation for a national regulatory authority (NRA) assessment of vaccines by the World Health Organization (WHO).', 34)

('The technical requirements to be submitted shall be the same as those submitted to the reference NRA of the ASEAN member country where the Certificate of Product Registration (CPR) was issued,” the guidelines state.', 4)

('TGA Notice China’s NMPA posts guidance on self-inspection of device quality systems China’s National Medical Products Administration (NMPA) has updated its guidance on the annual self-inspection of medical device quality management systems as part of a raft of changes that will take effect on 1 May. The updated guideline is one of three new or updated documents that NMPA will implement in a little over one month.', 22)

In [8]:

df

Out[8]:

|  | keywords | identifier | title | url | date | Long-Summary | Short-Summary |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | medical devices | device | https://www.mddionline.com/regulatory-quality/... | tactics for developing connected medical devices | https://www.mddionline.com/digital-health/tact... | 30-03-2022 | It is desirable to be an early provider of the... | Remedios will explore the potential of such st... |
| 1 | device | https://www.mddionline.com/regulatory-quality/... | cloudcath wins fda nod for connected device th... | https://www.mddionline.com/digital-health/clou... | 30-03-2022 | Dialysis Monitoring to Avoid Clinical Deterior... | Dialysis Monitoring to Avoid Clinical Deterior... |
| 2 | 510(k) | https://www.fdanews.com/articles/topic/106?page=5 | Orthofix Receives FDA’s 510(k) Clearance for i... | https://www.fdanews.com/articles/207065-orthof... | 22-03-2022 | Orthofix Medical has been granted the FDA’s 51... | Orthofix Medical has been granted the FDA’s 51... |
| 3 | advamed | https://www.fdanews.com/articles/topic/106?page=5 | AdvaMed Says COVID-19 Test Manufacturing Must ... | https://www.fdanews.com/articles/207064-advame... | 22-03-2022 | The device trade association AdvaMed has issue... | The device trade association AdvaMed has issue... |
| 4 | 510(k) | https://www.fdanews.com/articles/topic/106?page=5 | BioMérieux Gets FDA’s 510(k) Clearance for its... | https://www.fdanews.com/articles/207063-biom%C... | 22-03-2022 | In vitro diagnostics company bioMérieux’s Vite... | In vitro diagnostics company bioMérieux’s Vite... |
| 5 | device | https://www.fdanews.com/articles/topic/106?page=5 | Enteral Device Industry Phasing Out ‘Legacy’ E... | https://www.fdanews.com/articles/207044-entera... | 21-03-2022 | Manufacturers of enteral devices are phasing o... | Manufacturers of enteral devices are phasing o... |
| 6 | recall | https://www.fdanews.com/articles/topic/106?page=5 | FDA Provides Update on Celltrion’s Recall of S... | https://www.fdanews.com/articles/207041-fda-pr... | 21-03-2022 | The FDA has issued on update on Celltrion’s Fe... | The reason for the recall is a high number of ... |
| 7 | notified body | https://www.medtechdive.com/topic/medical-devi... | Notified body update dampens hopes of near-ter... | https://www.medtechdive.com/news/notified-body... | 30-03-2022 | The European Commission provided an update on ... | Two other notified bodies have progressed to t... |
| 8 | device | https://www.medtechdive.com/topic/medical-devi... | FDA asks Congress for 14% bump in device budge... | https://www.medtechdive.com/news/fda-congress-... | 29-03-2022 | The agency's request for more budget authority... | The agency's request for more budget authority... |
| 9 | device | https://www.medtechdive.com/topic/medical-devi... | MDR updates safety, clinical performance requi... | https://www.medtechdive.com/news/mdr-safety-pe... | 28-03-2022 | MDCG's additional paragraph states: "The manuf... | In combination with the manufacturer's (single... |
| 10 | mdufa | https://www.medtechdive.com/topic/medical-devi... | FDA sets terms for MDUFA V agreement | https://www.medtechdive.com/news/fda-mdufa-v-a... | 23-03-2022 | The agreement will help get the FDA back on tr... | The agreement will help get the FDA back on tr... |
| 11 | recall | https://www.medtechdive.com/topic/medical-devi... | Another Philips ventilator recall gets Class I... | https://www.medtechdive.com/news/another-phili... | 23-03-2022 | The quality standards of Philips' respiratory ... | The quality standards of Philips' respiratory ... |
| 12 | recall | https://www.medtechdive.com/topic/medical-devi... | FDA labels Philips 2018 field correction for v... | https://www.medtechdive.com/news/fda-labels-ph... | 22-03-2022 | In June, Philips initiated a recall of sleep a... | The FDA's most recent action is now labeling t... |
| 13 | designation | https://www.medtechdive.com/topic/medical-devi... | Dexcom's hospital glucose monitor leads latest... | https://www.medtechdive.com/news/dexcom-breakt... | 22-03-2022 | Dexcom has led the latest batch of FDA breakth... | After the start of the COVID-19 pandemic, the ... |
| 14 | medtech | https://www.medtechdive.com/topic/medical-devi... | French, German medtech groups call for at leas... | https://www.medtechdive.com/news/french-german... | 17-03-2022 | The French and German trade groups made the ca... | The French and German trade groups made the ca... |
| 15 | recall | device | https://www.medtechdive.com/topic/medical-devi... | FDA identified 28 suppliers unaware of Philips... | https://www.medtechdive.com/news/fda-identifie... | 16-03-2022 | Last Thursday, the FDA released an order direc... | Last Thursday, the FDA released an order direc... |
| 16 | medtech | https://www.medtechdive.com/topic/medical-devi... | US replaces EU as priority market for medtech ... | https://www.medtechdive.com/news/us-replaces-e... | 16-03-2022 | At the same time, FDA has set the target of ma... | In its most recent assessment, FDA found almos... |
| 17 | device | https://www.medtechdive.com/topic/medical-devi... | Steep drop in medical device reports on Bayer'... | https://www.medtechdive.com/news/drop-in-devic... | 15-03-2022 | While it is now years since Essure was sold in... | The webpage now features details of the agency... |
| 18 | device | https://www.medtechdive.com/topic/medical-devi... | Apyx's surgical device gets FDA warning on off... | https://www.medtechdive.com/news/apyxs-surgica... | 15-03-2022 | The reports to the agency describe "serious an... | The reports to the agency describe "serious an... |
| 19 | recall | device | https://www.medtechdive.com/topic/medical-devi... | FDA orders Philips to notify customers about s... | https://www.medtechdive.com/news/fda-orders-ph... | 11-03-2022 | The agency ordered Philips to notify all devic... | "The information currently available on Philip... |
| 20 | mdufa | https://www.medtechdive.com/topic/medical-devi... | FDA reaches MDUFA V agreement with industry | https://www.medtechdive.com/news/fda-reaches-m... | 09-03-2022 | The MDUFA V deal, which determines how much in... | "One of the FDA's priorities that was ultimate... |
| 21 | device | software | https://www.medtechdive.com/topic/medical-devi... | FDA warns of cyber vulnerabilities in medical ... | https://www.medtechdive.com/news/fda-cyber-vul... | 09-03-2022 | All versions of PTC's Axeda agent and desktop ... | All versions of PTC's Axeda agent and desktop ... |
| 22 | device | https://www.medtechdive.com/topic/medical-devi... | Medtronic, Nevro boosted by expansion of Medic... | https://www.medtechdive.com/news/medtronic-nev... | 09-03-2022 | Nevro said the Noridian update covers around 8... | Nevro said the Noridian update covers around 8... |
| 23 | mdufa | https://www.raps.org/news-and-articles/news-ar... | shuren apologizes for mdufa delay, says fda wi... | https://www.raps.org/news-and-articles/news-ar... | 30-03-2022 | At the start of the meeting committee Chair Fr... | At the start of the meeting committee Chair Fr... |
| 24 | approval | https://www.raps.org/news-and-articles/news-ar... | fda approvals roundup: pluvicto, cabenuva, fin... | https://www.raps.org/news-and-articles/news-ar... | 30-03-2022 | Approval of Pluvicto was based on findings fro... | New indications Cabenuva HIV regimen nabs expa... |
| 25 | medical devices | device | https://www.raps.org/news-and-articles/news-ar... | asia-pacific roundup: philippine fda seeks fee... | https://www.raps.org/news-and-articles/news-ar... | 29-03-2022 | The technical requirements to be submitted sha... | NMPA Notice (Chinese) India approves Novavax’s... |

In [9]:

from datetime import date

today = date.today()

# dd/mm/YY

d1 = today.strftime("%d-%m-%Y")

output = 'AIS\_data(Scraping+Summrization)\_'+d1+'.csv'

#df.to\_csv(output, encoding='utf-8-sig', index=False)

In [10]:

# l1 = df.values.tolist()

# for d1 in l1:

# print(tuple(d1), "\n\n")

# print("\*"\*100)

In [11]:

import pyodbc

server = "icdaue01db010.database.windows.net"

db1 = "ICDAUE01DW010"

uname = "A4028113"

pword = ""

#tcon = 'yes'

# Getting all the drivers

drivers = [item for item in pyodbc.drivers()]

print("driver:{}".format(drivers))

# Getting the desired driver name

drivers = [item for item in pyodbc.drivers()]

driver = drivers[4]

con\_string = f'DRIVER={driver};SERVER={server};DATABASE={db1};UID={uname};PWD={pword}'

print(con\_string)

cnxn = pyodbc.connect(con\_string)

cursor = cnxn.cursor()

query\_count = '''SELECT COUNT(Title) FROM [ais\_poc].[Article\_Details];'''

cursor.execute(query\_count) # It will return the number of rows affected

# for row in cursor:

# print("Number of records:", row)

for i in range(len(df)):

print(i, "\n\n\n")

keywords = df.loc[i,:]['keywords'].replace("'","''")

identifier = df.loc[i,:]['identifier'].replace("'","''")

title = df.loc[i,:]['title'].replace("'","''")

url = df.loc[i,:]['url']

date\_old = df.loc[i,:]['date'] # default YYYY-MM-DD Now: DD-MM-YYYY

date\_list = date\_old.split('-')

# print(date\_list)

date = date\_list[-1] + "-" + date\_list[-2] + "-" + date\_list[0]

# print(date)

long\_summary = df.loc[i,:]['Long-Summary'].replace("'","''")

short\_summary = df.loc[i,:]['Short-Summary'].replace("'","''")

# Writing the query for update and Insert

query\_main = f'''IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = '{title}') UPDATE [ais\_poc].[Article\_Details] SET Identifier = '{identifier}', Title = '{title}', Article\_URL = '{url}', Article\_Published\_Date = '{date}', Keywords = '{keywords}', Long\_Summary = '{long\_summary}', Short\_Summary = '{short\_summary}' WHERE Title = '{title}' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('{identifier}', '{title}', '{url}', '{date}', '{long\_summary}', '{short\_summary}', '{keywords}');'''

print(query\_main)

query\_commit = "COMMIT"

cursor.execute(query\_main)

cursor.execute(query\_commit)

driver:['PostgreSQL', 'MySQL', 'FreeTDS', 'MariaDB', 'ODBC Driver 18 for SQL Server']

DRIVER=ODBC Driver 18 for SQL Server;SERVER=icdaue01db010.database.windows.net;DATABASE=ICDAUE01DW010;UID=A4028113;PWD=

0

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'tactics for developing connected medical devices') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.mddionline.com/regulatory-quality/regulations', Title = 'tactics for developing connected medical devices', Article\_URL = 'https://www.mddionline.com/digital-health/tactics-developing-connected-medical-devices', Article\_Published\_Date = '2022-03-30', Keywords = 'medical devices | device', Long\_Summary = 'It is desirable to be an early provider of these new devices, so in order to reduce time-to-market, device companies need to move toward higher levels of concurrent collaboration among disparate development teams involved in traditional embedded design, application software, and other connected technologies.” Remedios will explore the potential of such strategies in the MD&M West conference session, "Outsprint Your Competition to Market Launch by Streamlining Your Collaboration Roadmap," held in Room 210AB April 12 from 9:30 – 10:15 a.m. “Attendees will learn how to establish stakeholder strategy alignment early on with collaboration among executive, technical, marketing, manufacturing, sales, and service teams,” Remedios said. “ Remedios will then moderate a panel discussion, Connected Device Design: Using Best Practices During the Product Development Process, shortly after in 208AB on April 12 from 10:30 – 11:15 a.m. He will be joined by panelists Tom Ulrich, Ph.D. and Chief Scientist, Tandem Diabetes Care; Jeff Gross, Chief Technology Officer, Canary Medical; and Patrick Bangert, Vice President of AI, Samsung, SDSA. Attendees of the panel discussion “will learn development best practices that maximize the stability of interoperative technologies and the regulatory landscape, including privacy and use-safety challenges associated with widely varying environmental and operating conditions.”', Short\_Summary = 'Remedios will explore the potential of such strategies in the MD&M West conference session, "Outsprint Your Competition to Market Launch by Streamlining Your Collaboration Roadmap," held in Room 210AB April 12 from 9:30 – 10:15 a.m. “Attendees will learn how to establish stakeholder strategy alignment early on with collaboration among executive, technical, marketing, manufacturing, sales, and service teams,” Remedios said. “ Remedios will then moderate a panel discussion, Connected Device Design: Using Best Practices During the Product Development Process, shortly after in 208AB on April 12 from 10:30 – 11:15 a.m. He will be joined by panelists Tom Ulrich, Ph.D. and Chief Scientist, Tandem Diabetes Care; Jeff Gross, Chief Technology Officer, Canary Medical; and Patrick Bangert, Vice President of AI, Samsung, SDSA.' WHERE Title = 'tactics for developing connected medical devices' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.mddionline.com/regulatory-quality/regulations', 'tactics for developing connected medical devices', 'https://www.mddionline.com/digital-health/tactics-developing-connected-medical-devices', '2022-03-30', 'It is desirable to be an early provider of these new devices, so in order to reduce time-to-market, device companies need to move toward higher levels of concurrent collaboration among disparate development teams involved in traditional embedded design, application software, and other connected technologies.” Remedios will explore the potential of such strategies in the MD&M West conference session, "Outsprint Your Competition to Market Launch by Streamlining Your Collaboration Roadmap," held in Room 210AB April 12 from 9:30 – 10:15 a.m. “Attendees will learn how to establish stakeholder strategy alignment early on with collaboration among executive, technical, marketing, manufacturing, sales, and service teams,” Remedios said. “ Remedios will then moderate a panel discussion, Connected Device Design: Using Best Practices During the Product Development Process, shortly after in 208AB on April 12 from 10:30 – 11:15 a.m. He will be joined by panelists Tom Ulrich, Ph.D. and Chief Scientist, Tandem Diabetes Care; Jeff Gross, Chief Technology Officer, Canary Medical; and Patrick Bangert, Vice President of AI, Samsung, SDSA. Attendees of the panel discussion “will learn development best practices that maximize the stability of interoperative technologies and the regulatory landscape, including privacy and use-safety challenges associated with widely varying environmental and operating conditions.”', 'Remedios will explore the potential of such strategies in the MD&M West conference session, "Outsprint Your Competition to Market Launch by Streamlining Your Collaboration Roadmap," held in Room 210AB April 12 from 9:30 – 10:15 a.m. “Attendees will learn how to establish stakeholder strategy alignment early on with collaboration among executive, technical, marketing, manufacturing, sales, and service teams,” Remedios said. “ Remedios will then moderate a panel discussion, Connected Device Design: Using Best Practices During the Product Development Process, shortly after in 208AB on April 12 from 10:30 – 11:15 a.m. He will be joined by panelists Tom Ulrich, Ph.D. and Chief Scientist, Tandem Diabetes Care; Jeff Gross, Chief Technology Officer, Canary Medical; and Patrick Bangert, Vice President of AI, Samsung, SDSA.', 'medical devices | device');

1

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'cloudcath wins fda nod for connected device that brings dialysis to the home') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.mddionline.com/regulatory-quality/regulations', Title = 'cloudcath wins fda nod for connected device that brings dialysis to the home', Article\_URL = 'https://www.mddionline.com/digital-health/cloudcath-wins-fda-nod-connected-device-brings-dialysis-home', Article\_Published\_Date = '2022-03-30', Keywords = 'device', Long\_Summary = 'Dialysis Monitoring to Avoid Clinical Deterioration “The CloudCath device is designed to support the clinician/patient partnership for at-home PD therapy,” said Elbadry, adding, “Actually, the entire dialysis ecosystem has a current and urgent goal to maximize use of home modalities.” With a cloud-based digital connection, the PD monitoring system continuously provides data that can tip a physician off to a brewing health issue. “ Changes in fluid turbidity are detected by CloudCath’s proprietary cloud-based algorithm and notifications are sent to clinicians and patients to alert them to seek additional medical evaluation.” Although focused on home PD, of course, the CloudCath System can also be used in healthcare settings like longterm care facilities and, in the rare case that a patient moves to a hospital and continues PD treatment, the CloudCath System could be used in a hospital setting,” said Elbadry.', Short\_Summary = 'Dialysis Monitoring to Avoid Clinical Deterioration “The CloudCath device is designed to support the clinician/patient partnership for at-home PD therapy,” said Elbadry, adding, “Actually, the entire dialysis ecosystem has a current and urgent goal to maximize use of home modalities.” Changes in fluid turbidity are detected by CloudCath’s proprietary cloud-based algorithm and notifications are sent to clinicians and patients to alert them to seek additional medical evaluation.”' WHERE Title = 'cloudcath wins fda nod for connected device that brings dialysis to the home' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.mddionline.com/regulatory-quality/regulations', 'cloudcath wins fda nod for connected device that brings dialysis to the home', 'https://www.mddionline.com/digital-health/cloudcath-wins-fda-nod-connected-device-brings-dialysis-home', '2022-03-30', 'Dialysis Monitoring to Avoid Clinical Deterioration “The CloudCath device is designed to support the clinician/patient partnership for at-home PD therapy,” said Elbadry, adding, “Actually, the entire dialysis ecosystem has a current and urgent goal to maximize use of home modalities.” With a cloud-based digital connection, the PD monitoring system continuously provides data that can tip a physician off to a brewing health issue. “ Changes in fluid turbidity are detected by CloudCath’s proprietary cloud-based algorithm and notifications are sent to clinicians and patients to alert them to seek additional medical evaluation.” Although focused on home PD, of course, the CloudCath System can also be used in healthcare settings like longterm care facilities and, in the rare case that a patient moves to a hospital and continues PD treatment, the CloudCath System could be used in a hospital setting,” said Elbadry.', 'Dialysis Monitoring to Avoid Clinical Deterioration “The CloudCath device is designed to support the clinician/patient partnership for at-home PD therapy,” said Elbadry, adding, “Actually, the entire dialysis ecosystem has a current and urgent goal to maximize use of home modalities.” Changes in fluid turbidity are detected by CloudCath’s proprietary cloud-based algorithm and notifications are sent to clinicians and patients to alert them to seek additional medical evaluation.”', 'device');

2

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'Orthofix Receives FDA’s 510(k) Clearance for its TrueLok EVO Ring Fixation System') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.fdanews.com/articles/topic/106?page=5', Title = 'Orthofix Receives FDA’s 510(k) Clearance for its TrueLok EVO Ring Fixation System', Article\_URL = 'https://www.fdanews.com/articles/207065-orthofix-receives-fdas-510k-clearance-for-its-truelok-evo-ring-fixation-system', Article\_Published\_Date = '2022-03-22', Keywords = '510(k)', Long\_Summary = 'Orthofix Medical has been granted the FDA’s 510(k) clearance for its TrueLok EVO ring fixation system (EVO is short for “evolution”).The external fixation device for the lower leg and foot is for use in complex limb reconstruction and deformity correction procedures, according to the Lewisville, Tex.-based company. The device, which features radiolucent rings and struts for clear radiographic visualization, is intended to let physicians better assess bone anatomy during surgery and postoperative care. TrueLok EVO is available as a preassembled frame in ready-to-use, single-use sterile packaging, which makes application easier, potentially saving time during surgery, the company said.', Short\_Summary = 'Orthofix Medical has been granted the FDA’s 510(k) clearance for its TrueLok EVO ring fixation system (EVO is short for “evolution”).The external fixation device for the lower leg and foot is for use in complex limb reconstruction and deformity correction procedures, according to the Lewisville, Tex.-based company. The device, which features radiolucent rings and struts for clear radiographic visualization, is intended to let physicians better assess bone anatomy during surgery and postoperative care. TrueLok EVO is available as a preassembled frame in ready-to-use, single-use sterile packaging, which makes application easier, potentially saving time during surgery, the company said.' WHERE Title = 'Orthofix Receives FDA’s 510(k) Clearance for its TrueLok EVO Ring Fixation System' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.fdanews.com/articles/topic/106?page=5', 'Orthofix Receives FDA’s 510(k) Clearance for its TrueLok EVO Ring Fixation System', 'https://www.fdanews.com/articles/207065-orthofix-receives-fdas-510k-clearance-for-its-truelok-evo-ring-fixation-system', '2022-03-22', 'Orthofix Medical has been granted the FDA’s 510(k) clearance for its TrueLok EVO ring fixation system (EVO is short for “evolution”).The external fixation device for the lower leg and foot is for use in complex limb reconstruction and deformity correction procedures, according to the Lewisville, Tex.-based company. The device, which features radiolucent rings and struts for clear radiographic visualization, is intended to let physicians better assess bone anatomy during surgery and postoperative care. TrueLok EVO is available as a preassembled frame in ready-to-use, single-use sterile packaging, which makes application easier, potentially saving time during surgery, the company said.', 'Orthofix Medical has been granted the FDA’s 510(k) clearance for its TrueLok EVO ring fixation system (EVO is short for “evolution”).The external fixation device for the lower leg and foot is for use in complex limb reconstruction and deformity correction procedures, according to the Lewisville, Tex.-based company. The device, which features radiolucent rings and struts for clear radiographic visualization, is intended to let physicians better assess bone anatomy during surgery and postoperative care. TrueLok EVO is available as a preassembled frame in ready-to-use, single-use sterile packaging, which makes application easier, potentially saving time during surgery, the company said.', '510(k)');

3

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'AdvaMed Says COVID-19 Test Manufacturing Must Be Beefed Up') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.fdanews.com/articles/topic/106?page=5', Title = 'AdvaMed Says COVID-19 Test Manufacturing Must Be Beefed Up', Article\_URL = 'https://www.fdanews.com/articles/207064-advamed-says-covid-19-test-manufacturing-must-be-beefed-up', Article\_Published\_Date = '2022-03-22', Keywords = 'advamed', Long\_Summary = 'The device trade association AdvaMed has issued an urgent call for more federal funding to produce COVID-19 diagnostic tests because the administration announced that its efforts would have to be scaled back unless Congress appropriates more money. “Should we face another wave of cases, we must be prepared to meet the needs of patients and public health, and we cannot do that without firm public-private commitments in place with test manufacturers,” said AdvaMed President and CEO Scott Whitaker. Among other measures, the association wants the federal government to partner with the device industry for “warm base manufacturing” arrangements. A warm base refers to facilities that would be constructed and commissioned, ready to quickly manufacture products on demand.', Short\_Summary = 'The device trade association AdvaMed has issued an urgent call for more federal funding to produce COVID-19 diagnostic tests because the administration announced that its efforts would have to be scaled back unless Congress appropriates more money. Among other measures, the association wants the federal government to partner with the device industry for “warm base manufacturing” arrangements.' WHERE Title = 'AdvaMed Says COVID-19 Test Manufacturing Must Be Beefed Up' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.fdanews.com/articles/topic/106?page=5', 'AdvaMed Says COVID-19 Test Manufacturing Must Be Beefed Up', 'https://www.fdanews.com/articles/207064-advamed-says-covid-19-test-manufacturing-must-be-beefed-up', '2022-03-22', 'The device trade association AdvaMed has issued an urgent call for more federal funding to produce COVID-19 diagnostic tests because the administration announced that its efforts would have to be scaled back unless Congress appropriates more money. “Should we face another wave of cases, we must be prepared to meet the needs of patients and public health, and we cannot do that without firm public-private commitments in place with test manufacturers,” said AdvaMed President and CEO Scott Whitaker. Among other measures, the association wants the federal government to partner with the device industry for “warm base manufacturing” arrangements. A warm base refers to facilities that would be constructed and commissioned, ready to quickly manufacture products on demand.', 'The device trade association AdvaMed has issued an urgent call for more federal funding to produce COVID-19 diagnostic tests because the administration announced that its efforts would have to be scaled back unless Congress appropriates more money. Among other measures, the association wants the federal government to partner with the device industry for “warm base manufacturing” arrangements.', 'advamed');

4

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'BioMérieux Gets FDA’s 510(k) Clearance for its Mass Spectrometry System') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.fdanews.com/articles/topic/106?page=5', Title = 'BioMérieux Gets FDA’s 510(k) Clearance for its Mass Spectrometry System', Article\_URL = 'https://www.fdanews.com/articles/207063-biom%C3%A9rieux-gets-fdas-510k-clearance-for-its-mass-spectrometry-system', Article\_Published\_Date = '2022-03-22', Keywords = '510(k)', Long\_Summary = 'In vitro diagnostics company bioMérieux’s Vitek MS Prime mass spectrometry identification system has received 510(k) clearance from the FDA.The compact benchtop system is integrated with the company’s fully automated Vitek 2 system for bacterial identification and antibiotic susceptibility testing. The Vitek MS Prime system allows for prioritization of urgent samples and continuous “load and go” operation, the company said.', Short\_Summary = 'In vitro diagnostics company bioMérieux’s Vitek MS Prime mass spectrometry identification system has received 510(k) clearance from the FDA.The compact benchtop system is integrated with the company’s fully automated Vitek 2 system for bacterial identification and antibiotic susceptibility testing. The Vitek MS Prime system allows for prioritization of urgent samples and continuous “load and go” operation, the company said.' WHERE Title = 'BioMérieux Gets FDA’s 510(k) Clearance for its Mass Spectrometry System' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.fdanews.com/articles/topic/106?page=5', 'BioMérieux Gets FDA’s 510(k) Clearance for its Mass Spectrometry System', 'https://www.fdanews.com/articles/207063-biom%C3%A9rieux-gets-fdas-510k-clearance-for-its-mass-spectrometry-system', '2022-03-22', 'In vitro diagnostics company bioMérieux’s Vitek MS Prime mass spectrometry identification system has received 510(k) clearance from the FDA.The compact benchtop system is integrated with the company’s fully automated Vitek 2 system for bacterial identification and antibiotic susceptibility testing. The Vitek MS Prime system allows for prioritization of urgent samples and continuous “load and go” operation, the company said.', 'In vitro diagnostics company bioMérieux’s Vitek MS Prime mass spectrometry identification system has received 510(k) clearance from the FDA.The compact benchtop system is integrated with the company’s fully automated Vitek 2 system for bacterial identification and antibiotic susceptibility testing. The Vitek MS Prime system allows for prioritization of urgent samples and continuous “load and go” operation, the company said.', '510(k)');

5

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'Enteral Device Industry Phasing Out ‘Legacy’ Enteral Connectors') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.fdanews.com/articles/topic/106?page=5', Title = 'Enteral Device Industry Phasing Out ‘Legacy’ Enteral Connectors', Article\_URL = 'https://www.fdanews.com/articles/207044-enteral-device-industry-phasing-out-legacy-enteral-connectors', Article\_Published\_Date = '2022-03-21', Keywords = 'device', Long\_Summary = 'Manufacturers of enteral devices are phasing out their production of older-style enteral connectors in North America to improve patient safety, a trade group says. The Global Enteral Device Supplier Association says its members and affiliates in the enteral feeding device market are increasingly converting to ENFit connectors that comply with the International Organization for Standardization’s ISO 80369-3 standard and they are updating their timelines for the phase-out of the older-style devices. The trade group says the industry’s switch to ENFit connectors will reduce the “risks of potentially fatal medical device misconnections and minimize unintentional disconnections.” And the use of one universal technology should also mitigate supply-chain interruptions for enteral small-bore connectors, the group said.', Short\_Summary = 'Manufacturers of enteral devices are phasing out their production of older-style enteral connectors in North America to improve patient safety, a trade group says. The trade group says the industry’s switch to ENFit connectors will reduce the “risks of potentially fatal medical device misconnections and minimize unintentional disconnections.”' WHERE Title = 'Enteral Device Industry Phasing Out ‘Legacy’ Enteral Connectors' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.fdanews.com/articles/topic/106?page=5', 'Enteral Device Industry Phasing Out ‘Legacy’ Enteral Connectors', 'https://www.fdanews.com/articles/207044-enteral-device-industry-phasing-out-legacy-enteral-connectors', '2022-03-21', 'Manufacturers of enteral devices are phasing out their production of older-style enteral connectors in North America to improve patient safety, a trade group says. The Global Enteral Device Supplier Association says its members and affiliates in the enteral feeding device market are increasingly converting to ENFit connectors that comply with the International Organization for Standardization’s ISO 80369-3 standard and they are updating their timelines for the phase-out of the older-style devices. The trade group says the industry’s switch to ENFit connectors will reduce the “risks of potentially fatal medical device misconnections and minimize unintentional disconnections.” And the use of one universal technology should also mitigate supply-chain interruptions for enteral small-bore connectors, the group said.', 'Manufacturers of enteral devices are phasing out their production of older-style enteral connectors in North America to improve patient safety, a trade group says. The trade group says the industry’s switch to ENFit connectors will reduce the “risks of potentially fatal medical device misconnections and minimize unintentional disconnections.”', 'device');

6

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'FDA Provides Update on Celltrion’s Recall of Some Lots of its COVID-19 Test') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.fdanews.com/articles/topic/106?page=5', Title = 'FDA Provides Update on Celltrion’s Recall of Some Lots of its COVID-19 Test', Article\_URL = 'https://www.fdanews.com/articles/207041-fda-provides-update-on-celltrions-recall-of-some-lots-of-its-covid-19-test', Article\_Published\_Date = '2022-03-21', Keywords = 'recall', Long\_Summary = 'The FDA has issued on update on Celltrion’s Feb. 28 recall of specific lots of its DiaTrust COVID-19 Ag rapid test, deeming it a Class 1 recall because of the risk of serious injury or death. The reason for the recall is a high number of false-positive reports and unauthorized shelf life labeling. The 45,500 affected products with the product code 83QKP were distributed from June 2 to Dec. 21, 2021.The FDA says that although it has not received any reports of injuries, adverse health consequences or death due to use of the affected test kits, “false-positive or false-negative results from improper use of these tests could lead to further exposure of uninfected individuals to the SARS-CoV-2 virus. The agency also noted “serious injury risks if someone who is not trained to collect a nasopharyngeal swab sample attempts to do so.”', Short\_Summary = 'The reason for the recall is a high number of false-positive reports and unauthorized shelf life labeling. The 45,500 affected products with the product code 83QKP were distributed from June 2 to Dec. 21, 2021.The FDA says that although it has not received any reports of injuries, adverse health consequences or death due to use of the affected test kits, “false-positive or false-negative results from improper use of these tests could lead to further exposure of uninfected individuals to the SARS-CoV-2 virus.' WHERE Title = 'FDA Provides Update on Celltrion’s Recall of Some Lots of its COVID-19 Test' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.fdanews.com/articles/topic/106?page=5', 'FDA Provides Update on Celltrion’s Recall of Some Lots of its COVID-19 Test', 'https://www.fdanews.com/articles/207041-fda-provides-update-on-celltrions-recall-of-some-lots-of-its-covid-19-test', '2022-03-21', 'The FDA has issued on update on Celltrion’s Feb. 28 recall of specific lots of its DiaTrust COVID-19 Ag rapid test, deeming it a Class 1 recall because of the risk of serious injury or death. The reason for the recall is a high number of false-positive reports and unauthorized shelf life labeling. The 45,500 affected products with the product code 83QKP were distributed from June 2 to Dec. 21, 2021.The FDA says that although it has not received any reports of injuries, adverse health consequences or death due to use of the affected test kits, “false-positive or false-negative results from improper use of these tests could lead to further exposure of uninfected individuals to the SARS-CoV-2 virus. The agency also noted “serious injury risks if someone who is not trained to collect a nasopharyngeal swab sample attempts to do so.”', 'The reason for the recall is a high number of false-positive reports and unauthorized shelf life labeling. The 45,500 affected products with the product code 83QKP were distributed from June 2 to Dec. 21, 2021.The FDA says that although it has not received any reports of injuries, adverse health consequences or death due to use of the affected test kits, “false-positive or false-negative results from improper use of these tests could lead to further exposure of uninfected individuals to the SARS-CoV-2 virus.', 'recall');

7

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'Notified body update dampens hopes of near-term surge in IVDR capacity') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'Notified body update dampens hopes of near-term surge in IVDR capacity', Article\_URL = 'https://www.medtechdive.com/news/notified-body-update-ivdr-mdr/621238/', Article\_Published\_Date = '2022-03-30', Keywords = 'notified body', Long\_Summary = 'The European Commission provided an update on the progress of notified body applications under the new regulations, revealing a growing pipeline of submissions that are approaching medical device designation but little hope of a near-term surge in in vitro diagnostic capacity. The Commission''s March 21 update of the notified body pipeline reveals limited progress of the push to add more organizations capable of certifying products under the In Vitro Diagnostic Regulation. Two other notified bodies have progressed to the joint assessment team corrective action and preventive action (JAT CAPA) review stage since December, but none have made it past. The latest update, which covers the situation as of March 21, reveals a clutch of notified bodies has now cleared the JAT CAPA review stage, putting them a handful of steps from the end of the MDR designation process.', Short\_Summary = 'Two other notified bodies have progressed to the joint assessment team corrective action and preventive action (JAT CAPA) review stage since December, but none have made it past. The latest update, which covers the situation as of March 21, reveals a clutch of notified bodies has now cleared the JAT CAPA review stage, putting them a handful of steps from the end of the MDR designation process.' WHERE Title = 'Notified body update dampens hopes of near-term surge in IVDR capacity' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'Notified body update dampens hopes of near-term surge in IVDR capacity', 'https://www.medtechdive.com/news/notified-body-update-ivdr-mdr/621238/', '2022-03-30', 'The European Commission provided an update on the progress of notified body applications under the new regulations, revealing a growing pipeline of submissions that are approaching medical device designation but little hope of a near-term surge in in vitro diagnostic capacity. The Commission''s March 21 update of the notified body pipeline reveals limited progress of the push to add more organizations capable of certifying products under the In Vitro Diagnostic Regulation. Two other notified bodies have progressed to the joint assessment team corrective action and preventive action (JAT CAPA) review stage since December, but none have made it past. The latest update, which covers the situation as of March 21, reveals a clutch of notified bodies has now cleared the JAT CAPA review stage, putting them a handful of steps from the end of the MDR designation process.', 'Two other notified bodies have progressed to the joint assessment team corrective action and preventive action (JAT CAPA) review stage since December, but none have made it past. The latest update, which covers the situation as of March 21, reveals a clutch of notified bodies has now cleared the JAT CAPA review stage, putting them a handful of steps from the end of the MDR designation process.', 'notified body');

8

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'FDA asks Congress for 14% bump in device budget for supply chain, cybersecurity programs') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'FDA asks Congress for 14% bump in device budget for supply chain, cybersecurity programs', Article\_URL = 'https://www.medtechdive.com/news/fda-congress-device-budget-supply-chain-cyber/621156/', Article\_Published\_Date = '2022-03-29', Keywords = 'device', Long\_Summary = 'The agency''s request for more budget authority from Congress is split fairly evenly between money for medical product safety and crosscutting, a term that captures work such as capacity building and inspection activities that span multiple departments. At $31.4 million, the safety program is in line to receive slightly more money, reflecting the fact that it covers the single biggest change in FDA''s medical device spending plans for fiscal 2023, namely RSCSP. The establishment of a permanent device shortages program will help ensure U.S. patients and health care providers have access to the critical devices they need and help reduce U.S. dependence on devices from other nations by enhancing CDRH''s capacity to enable rapid intervention to prevent and mitigate supply chain interruptions," the FDA wrote in its budget justification. "The FDA is also seeking a further $26.4 million and 24 FTEs in relation to crosscutting work such as capacity building and inspection activities that span multiple departments.', Short\_Summary = 'The agency''s request for more budget authority from Congress is split fairly evenly between money for medical product safety and crosscutting, a term that captures work such as capacity building and inspection activities that span multiple departments. "The FDA is also seeking a further $26.4 million and 24 FTEs in relation to crosscutting work such as capacity building and inspection activities that span multiple departments.' WHERE Title = 'FDA asks Congress for 14% bump in device budget for supply chain, cybersecurity programs' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'FDA asks Congress for 14% bump in device budget for supply chain, cybersecurity programs', 'https://www.medtechdive.com/news/fda-congress-device-budget-supply-chain-cyber/621156/', '2022-03-29', 'The agency''s request for more budget authority from Congress is split fairly evenly between money for medical product safety and crosscutting, a term that captures work such as capacity building and inspection activities that span multiple departments. At $31.4 million, the safety program is in line to receive slightly more money, reflecting the fact that it covers the single biggest change in FDA''s medical device spending plans for fiscal 2023, namely RSCSP. The establishment of a permanent device shortages program will help ensure U.S. patients and health care providers have access to the critical devices they need and help reduce U.S. dependence on devices from other nations by enhancing CDRH''s capacity to enable rapid intervention to prevent and mitigate supply chain interruptions," the FDA wrote in its budget justification. "The FDA is also seeking a further $26.4 million and 24 FTEs in relation to crosscutting work such as capacity building and inspection activities that span multiple departments.', 'The agency''s request for more budget authority from Congress is split fairly evenly between money for medical product safety and crosscutting, a term that captures work such as capacity building and inspection activities that span multiple departments. "The FDA is also seeking a further $26.4 million and 24 FTEs in relation to crosscutting work such as capacity building and inspection activities that span multiple departments.', 'device');

9

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'MDR updates safety, clinical performance requirement for high-risk devices') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'MDR updates safety, clinical performance requirement for high-risk devices', Article\_URL = 'https://www.medtechdive.com/news/mdr-safety-performance-requirement-high-risk-devices/621089/', Article\_Published\_Date = '2022-03-28', Keywords = 'device', Long\_Summary = 'MDCG''s additional paragraph states: "The manufacturer will assign to the SSCP an identifier (reference number) that within the manufacturer''s management system is unique to that SSCP and will remain the same for the entire lifetime of the SCP. In combination with the manufacturer''s (single registration number) this will allow for the unique identification of the SSCP in EUDAMED and in EU."The updated template features "manufacturer’s reference number for the SSCP" at the top of the list of elements MDCG recommends manufacturers include in their summaries. MDCG also revised another section so it states the summary can be associated with one or multiple basic unique device identification - device identifiers (UDI-DIs). The 2019 guide states the SSCP is "associated to one unique Basic UDI-DI."MDCG''s update comes against a backdrop of continued debate about the implementation of MDR.', Short\_Summary = 'In combination with the manufacturer''s (single registration number) this will allow for the unique identification of the SSCP in EUDAMED and in EU."The updated template features "manufacturer’s reference number for the SSCP" at the top of the list of elements MDCG recommends manufacturers include in their summaries. The 2019 guide states the SSCP is "associated to one unique Basic UDI-DI."MDCG''s update comes against a backdrop of continued debate about the implementation of MDR.' WHERE Title = 'MDR updates safety, clinical performance requirement for high-risk devices' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'MDR updates safety, clinical performance requirement for high-risk devices', 'https://www.medtechdive.com/news/mdr-safety-performance-requirement-high-risk-devices/621089/', '2022-03-28', 'MDCG''s additional paragraph states: "The manufacturer will assign to the SSCP an identifier (reference number) that within the manufacturer''s management system is unique to that SSCP and will remain the same for the entire lifetime of the SCP. In combination with the manufacturer''s (single registration number) this will allow for the unique identification of the SSCP in EUDAMED and in EU."The updated template features "manufacturer’s reference number for the SSCP" at the top of the list of elements MDCG recommends manufacturers include in their summaries. MDCG also revised another section so it states the summary can be associated with one or multiple basic unique device identification - device identifiers (UDI-DIs). The 2019 guide states the SSCP is "associated to one unique Basic UDI-DI."MDCG''s update comes against a backdrop of continued debate about the implementation of MDR.', 'In combination with the manufacturer''s (single registration number) this will allow for the unique identification of the SSCP in EUDAMED and in EU."The updated template features "manufacturer’s reference number for the SSCP" at the top of the list of elements MDCG recommends manufacturers include in their summaries. The 2019 guide states the SSCP is "associated to one unique Basic UDI-DI."MDCG''s update comes against a backdrop of continued debate about the implementation of MDR.', 'device');

10

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'FDA sets terms for MDUFA V agreement') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'FDA sets terms for MDUFA V agreement', Article\_URL = 'https://www.medtechdive.com/news/fda-mdufa-v-agreement/620888/', Article\_Published\_Date = '2022-03-23', Keywords = 'mdufa', Long\_Summary = 'The agreement will help get the FDA back on track after several years of grappling with the COVID pandemic and introduces new accountability measures related to hiring targets, accrual and use of carryover balance. Jeff Shuren, director of the FDA''s Center for Devices and Radiological Health, said in a news release that the new agreement "represents a substantial investment in the future of the agency''s medical device program and would provide for important improvements, including new hiring targets, greater engagement with developers of innovative technologies based on lessons learned from the pandemic, broadened international harmonization efforts and expanded opportunities to ensure patient perspectives are an integral part of medical device development. For premarket approval submissions received in 2023 and 2024, the FDA has set a goal of 290 days to reach a decision. For 510(k) submissions, the FDA has set a goal of 128 days for 2023, shortening to 112 days starting in 2025.', Short\_Summary = 'The agreement will help get the FDA back on track after several years of grappling with the COVID pandemic and introduces new accountability measures related to hiring targets, accrual and use of carryover balance. Jeff Shuren, director of the FDA''s Center for Devices and Radiological Health, said in a news release that the new agreement "represents a substantial investment in the future of the agency''s medical device program and would provide for important improvements, including new hiring targets, greater engagement with developers of innovative technologies based on lessons learned from the pandemic, broadened international harmonization efforts and expanded opportunities to ensure patient perspectives are an integral part of medical device development.' WHERE Title = 'FDA sets terms for MDUFA V agreement' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'FDA sets terms for MDUFA V agreement', 'https://www.medtechdive.com/news/fda-mdufa-v-agreement/620888/', '2022-03-23', 'The agreement will help get the FDA back on track after several years of grappling with the COVID pandemic and introduces new accountability measures related to hiring targets, accrual and use of carryover balance. Jeff Shuren, director of the FDA''s Center for Devices and Radiological Health, said in a news release that the new agreement "represents a substantial investment in the future of the agency''s medical device program and would provide for important improvements, including new hiring targets, greater engagement with developers of innovative technologies based on lessons learned from the pandemic, broadened international harmonization efforts and expanded opportunities to ensure patient perspectives are an integral part of medical device development. For premarket approval submissions received in 2023 and 2024, the FDA has set a goal of 290 days to reach a decision. For 510(k) submissions, the FDA has set a goal of 128 days for 2023, shortening to 112 days starting in 2025.', 'The agreement will help get the FDA back on track after several years of grappling with the COVID pandemic and introduces new accountability measures related to hiring targets, accrual and use of carryover balance. Jeff Shuren, director of the FDA''s Center for Devices and Radiological Health, said in a news release that the new agreement "represents a substantial investment in the future of the agency''s medical device program and would provide for important improvements, including new hiring targets, greater engagement with developers of innovative technologies based on lessons learned from the pandemic, broadened international harmonization efforts and expanded opportunities to ensure patient perspectives are an integral part of medical device development.', 'mdufa');

11

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'Another Philips ventilator recall gets Class I label from the FDA') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'Another Philips ventilator recall gets Class I label from the FDA', Article\_URL = 'https://www.medtechdive.com/news/another-philips-recall-class-i-label-fda/620854/', Article\_Published\_Date = '2022-03-23', Keywords = 'recall', Long\_Summary = 'The quality standards of Philips'' respiratory business have been in the spotlight since the company began recalling millions of sleep apnea devices and ventilators over concerns the sound abatement foam may break down and expose patients to toxic chemicals. A separate recall of V60 ventilators started weeks later in response to the discovery the devices may provide the patient with a lower oxygen flow rate. Philips began the latest recall of V60 ventilators in January. News of the recall comes months after Philips expanded its program to repair and replace devices that use the potentially harmful sound abatement foam.', Short\_Summary = 'The quality standards of Philips'' respiratory business have been in the spotlight since the company began recalling millions of sleep apnea devices and ventilators over concerns the sound abatement foam may break down and expose patients to toxic chemicals. A separate recall of V60 ventilators started weeks later in response to the discovery the devices may provide the patient with a lower oxygen flow rate.' WHERE Title = 'Another Philips ventilator recall gets Class I label from the FDA' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'Another Philips ventilator recall gets Class I label from the FDA', 'https://www.medtechdive.com/news/another-philips-recall-class-i-label-fda/620854/', '2022-03-23', 'The quality standards of Philips'' respiratory business have been in the spotlight since the company began recalling millions of sleep apnea devices and ventilators over concerns the sound abatement foam may break down and expose patients to toxic chemicals. A separate recall of V60 ventilators started weeks later in response to the discovery the devices may provide the patient with a lower oxygen flow rate. Philips began the latest recall of V60 ventilators in January. News of the recall comes months after Philips expanded its program to repair and replace devices that use the potentially harmful sound abatement foam.', 'The quality standards of Philips'' respiratory business have been in the spotlight since the company began recalling millions of sleep apnea devices and ventilators over concerns the sound abatement foam may break down and expose patients to toxic chemicals. A separate recall of V60 ventilators started weeks later in response to the discovery the devices may provide the patient with a lower oxygen flow rate.', 'recall');

12

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'FDA labels Philips 2018 field correction for ventilators a Class I recall') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'FDA labels Philips 2018 field correction for ventilators a Class I recall', Article\_URL = 'https://www.medtechdive.com/news/fda-labels-philips-correction-class-i-recall/620804/', Article\_Published\_Date = '2022-03-22', Keywords = 'recall', Long\_Summary = 'In June, Philips initiated a recall of sleep apnea and ventilator machines due to safety risks associated with polyester-based polyurethane (PE-PUR) foam used to dampen the sound of the devices. The FDA''s most recent action is now labeling the 2018 corrective action from Philips a Class I recall; the agency created an entry in its recall database on March 18.The agency discovered the corrective action during a recent facility inspection following the June recall. In the FDA''s facility inspection form, called a Form 483, the agency wrote that the company did not notify the agency despite having reports of foam breaking down in Trilogy and other machines as early as 2014.The field correction was initiated in response to several complaints and at least one failure from a Trilogy machine caused by foam degradation, and the foam was later found to be "mutagenic, cytotoxic, carcinogenic, and non-biocompatible. "According to the March 18 database entry, the Class I recall impacts Trilogy 100/200, Garbin Plus, Aeris and LifeVent Continuous Ventilators machines.', Short\_Summary = 'The FDA''s most recent action is now labeling the 2018 corrective action from Philips a Class I recall; the agency created an entry in its recall database on March 18.The agency discovered the corrective action during a recent facility inspection following the June recall. In the FDA''s facility inspection form, called a Form 483, the agency wrote that the company did not notify the agency despite having reports of foam breaking down in Trilogy and other machines as early as 2014.The field correction was initiated in response to several complaints and at least one failure from a Trilogy machine caused by foam degradation, and the foam was later found to be "mutagenic, cytotoxic, carcinogenic, and non-biocompatible.' WHERE Title = 'FDA labels Philips 2018 field correction for ventilators a Class I recall' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'FDA labels Philips 2018 field correction for ventilators a Class I recall', 'https://www.medtechdive.com/news/fda-labels-philips-correction-class-i-recall/620804/', '2022-03-22', 'In June, Philips initiated a recall of sleep apnea and ventilator machines due to safety risks associated with polyester-based polyurethane (PE-PUR) foam used to dampen the sound of the devices. The FDA''s most recent action is now labeling the 2018 corrective action from Philips a Class I recall; the agency created an entry in its recall database on March 18.The agency discovered the corrective action during a recent facility inspection following the June recall. In the FDA''s facility inspection form, called a Form 483, the agency wrote that the company did not notify the agency despite having reports of foam breaking down in Trilogy and other machines as early as 2014.The field correction was initiated in response to several complaints and at least one failure from a Trilogy machine caused by foam degradation, and the foam was later found to be "mutagenic, cytotoxic, carcinogenic, and non-biocompatible. "According to the March 18 database entry, the Class I recall impacts Trilogy 100/200, Garbin Plus, Aeris and LifeVent Continuous Ventilators machines.', 'The FDA''s most recent action is now labeling the 2018 corrective action from Philips a Class I recall; the agency created an entry in its recall database on March 18.The agency discovered the corrective action during a recent facility inspection following the June recall. In the FDA''s facility inspection form, called a Form 483, the agency wrote that the company did not notify the agency despite having reports of foam breaking down in Trilogy and other machines as early as 2014.The field correction was initiated in response to several complaints and at least one failure from a Trilogy machine caused by foam degradation, and the foam was later found to be "mutagenic, cytotoxic, carcinogenic, and non-biocompatible.', 'recall');

13

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'Dexcom''s hospital glucose monitor leads latest FDA breakthrough designations') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'Dexcom''s hospital glucose monitor leads latest FDA breakthrough designations', Article\_URL = 'https://www.medtechdive.com/news/dexcom-breakthrough-designation-hospital-glucose-monitor/620774/', Article\_Published\_Date = '2022-03-22', Keywords = 'designation', Long\_Summary = 'Dexcom has led the latest batch of FDA breakthrough device designations, securing the regulatory privileges for a version of its continuous glucose monitor technology designed for use in hospital settings. After the start of the COVID-19 pandemic, the FDA issued guidance allowing glucose monitors indicated for home use to be used in a hospital setting, letting patients track and report their own blood glucose levels to reduce health care workers'' exposure to the virus. Insightec disclosed the breakthrough designation alongside news that FDA has granted its request to trial the device in combination with Merck''s checkpoint inhibitor Keytruda in NSCLC that has metastasized to the brain, and to enhance the efficacy of liquid biopsy for recurrence monitoring of patients with primary brain cancer. AltPep received breakthrough status for a blood test to detect Alzheimer''s disease.', Short\_Summary = 'After the start of the COVID-19 pandemic, the FDA issued guidance allowing glucose monitors indicated for home use to be used in a hospital setting, letting patients track and report their own blood glucose levels to reduce health care workers'' exposure to the virus. Insightec disclosed the breakthrough designation alongside news that FDA has granted its request to trial the device in combination with Merck''s checkpoint inhibitor Keytruda in NSCLC that has metastasized to the brain, and to enhance the efficacy of liquid biopsy for recurrence monitoring of patients with primary brain cancer.' WHERE Title = 'Dexcom''s hospital glucose monitor leads latest FDA breakthrough designations' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'Dexcom''s hospital glucose monitor leads latest FDA breakthrough designations', 'https://www.medtechdive.com/news/dexcom-breakthrough-designation-hospital-glucose-monitor/620774/', '2022-03-22', 'Dexcom has led the latest batch of FDA breakthrough device designations, securing the regulatory privileges for a version of its continuous glucose monitor technology designed for use in hospital settings. After the start of the COVID-19 pandemic, the FDA issued guidance allowing glucose monitors indicated for home use to be used in a hospital setting, letting patients track and report their own blood glucose levels to reduce health care workers'' exposure to the virus. Insightec disclosed the breakthrough designation alongside news that FDA has granted its request to trial the device in combination with Merck''s checkpoint inhibitor Keytruda in NSCLC that has metastasized to the brain, and to enhance the efficacy of liquid biopsy for recurrence monitoring of patients with primary brain cancer. AltPep received breakthrough status for a blood test to detect Alzheimer''s disease.', 'After the start of the COVID-19 pandemic, the FDA issued guidance allowing glucose monitors indicated for home use to be used in a hospital setting, letting patients track and report their own blood glucose levels to reduce health care workers'' exposure to the virus. Insightec disclosed the breakthrough designation alongside news that FDA has granted its request to trial the device in combination with Merck''s checkpoint inhibitor Keytruda in NSCLC that has metastasized to the brain, and to enhance the efficacy of liquid biopsy for recurrence monitoring of patients with primary brain cancer.', 'designation');

14

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'French, German medtech groups call for at least 2-year extension of MDR''s transition period') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'French, German medtech groups call for at least 2-year extension of MDR''s transition period', Article\_URL = 'https://www.medtechdive.com/news/french-german-medtech-groups-extension-mdr/620551/', Article\_Published\_Date = '2022-03-17', Keywords = 'medtech', Long\_Summary = 'The French and German trade groups made the case that despite the MDR going into effect last year, key parts of the necessary infrastructure are still not fully operational, creating challenges in particular for small- and medium-sized medtech companies that are reaching the limits of what is feasible when it comes to the certification of new and existing devices. To address the backlog in the certification of existing products, BVMed and Snitem want to see the designation period for notified bodies shortened, ongoing assessments streamlined and incentives set for further applications. MedTech Europe for some time has warned that although the new regulatory regime reached its date of application in 2021, significant challenges remain unresolved that could negatively impact the medtech sector including limited capacity among notified bodies, especially for certification of new and innovative devices. This is especially true for many small and medium enterprises, who contribute a significant portion of Europe''s medical device innovations," MedTech Europe said in May 2021 when MDR went in effect.', Short\_Summary = 'The French and German trade groups made the case that despite the MDR going into effect last year, key parts of the necessary infrastructure are still not fully operational, creating challenges in particular for small- and medium-sized medtech companies that are reaching the limits of what is feasible when it comes to the certification of new and existing devices. MedTech Europe for some time has warned that although the new regulatory regime reached its date of application in 2021, significant challenges remain unresolved that could negatively impact the medtech sector including limited capacity among notified bodies, especially for certification of new and innovative devices.' WHERE Title = 'French, German medtech groups call for at least 2-year extension of MDR''s transition period' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'French, German medtech groups call for at least 2-year extension of MDR''s transition period', 'https://www.medtechdive.com/news/french-german-medtech-groups-extension-mdr/620551/', '2022-03-17', 'The French and German trade groups made the case that despite the MDR going into effect last year, key parts of the necessary infrastructure are still not fully operational, creating challenges in particular for small- and medium-sized medtech companies that are reaching the limits of what is feasible when it comes to the certification of new and existing devices. To address the backlog in the certification of existing products, BVMed and Snitem want to see the designation period for notified bodies shortened, ongoing assessments streamlined and incentives set for further applications. MedTech Europe for some time has warned that although the new regulatory regime reached its date of application in 2021, significant challenges remain unresolved that could negatively impact the medtech sector including limited capacity among notified bodies, especially for certification of new and innovative devices. This is especially true for many small and medium enterprises, who contribute a significant portion of Europe''s medical device innovations," MedTech Europe said in May 2021 when MDR went in effect.', 'The French and German trade groups made the case that despite the MDR going into effect last year, key parts of the necessary infrastructure are still not fully operational, creating challenges in particular for small- and medium-sized medtech companies that are reaching the limits of what is feasible when it comes to the certification of new and existing devices. MedTech Europe for some time has warned that although the new regulatory regime reached its date of application in 2021, significant challenges remain unresolved that could negatively impact the medtech sector including limited capacity among notified bodies, especially for certification of new and innovative devices.', 'medtech');

15

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'FDA identified 28 suppliers unaware of Philips sleep device recall') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'FDA identified 28 suppliers unaware of Philips sleep device recall', Article\_URL = 'https://www.medtechdive.com/news/fda-identified-suppliers-unaware-philips-recall/620482/', Article\_Published\_Date = '2022-03-16', Keywords = 'recall | device', Long\_Summary = 'Last Thursday, the FDA released an order directing Philips to notify all of its customers regarding the recall of sleep apnea and ventilator machines, after the agency determined the company had failed to adequately communicate the recall and the health risks facing patients if affected devices were still used. In a six-page letter to Philips, the FDA said that the order comes due to "the significant period of time that has transpired since the initiation of the recall, and Philips'' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons … who should be notified, of the recall and the health risks presented by the Recalled Products. Philips initiated a recall in June due to health risks associated with the use of certain sleep apnea and ventilator machines. Along with patients and customers not being aware of the recall, the FDA wrote in its letter to the company that "it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products.', Short\_Summary = 'Last Thursday, the FDA released an order directing Philips to notify all of its customers regarding the recall of sleep apnea and ventilator machines, after the agency determined the company had failed to adequately communicate the recall and the health risks facing patients if affected devices were still used. In a six-page letter to Philips, the FDA said that the order comes due to "the significant period of time that has transpired since the initiation of the recall, and Philips'' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons … who should be notified, of the recall and the health risks presented by the Recalled Products.' WHERE Title = 'FDA identified 28 suppliers unaware of Philips sleep device recall' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'FDA identified 28 suppliers unaware of Philips sleep device recall', 'https://www.medtechdive.com/news/fda-identified-suppliers-unaware-philips-recall/620482/', '2022-03-16', 'Last Thursday, the FDA released an order directing Philips to notify all of its customers regarding the recall of sleep apnea and ventilator machines, after the agency determined the company had failed to adequately communicate the recall and the health risks facing patients if affected devices were still used. In a six-page letter to Philips, the FDA said that the order comes due to "the significant period of time that has transpired since the initiation of the recall, and Philips'' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons … who should be notified, of the recall and the health risks presented by the Recalled Products. Philips initiated a recall in June due to health risks associated with the use of certain sleep apnea and ventilator machines. Along with patients and customers not being aware of the recall, the FDA wrote in its letter to the company that "it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products.', 'Last Thursday, the FDA released an order directing Philips to notify all of its customers regarding the recall of sleep apnea and ventilator machines, after the agency determined the company had failed to adequately communicate the recall and the health risks facing patients if affected devices were still used. In a six-page letter to Philips, the FDA said that the order comes due to "the significant period of time that has transpired since the initiation of the recall, and Philips'' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons … who should be notified, of the recall and the health risks presented by the Recalled Products.', 'recall | device');

16

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'US replaces EU as priority market for medtech industry: survey') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'US replaces EU as priority market for medtech industry: survey', Article\_URL = 'https://www.medtechdive.com/news/us-replaces-eu-priority-market-medtechs/620450/', Article\_Published\_Date = '2022-03-16', Keywords = 'medtech', Long\_Summary = 'At the same time, FDA has set the target of making the U.S. the priority market for developers of novel devices. In its most recent assessment, FDA found almost two-third of manufacturers of novel technology devices plan to bring their products to the U.S. first or in parallel with other major markets. Only 22% of respondents said the EU pathway for regulatory approval of standard medical technology is predictable. There is still room to improve for FDA, particularly with 33% of respondents viewing its digital product pathway as predictable, but there was broad support for some of its key initiatives and a perception that it now offers a clearer path to market than the EU.In the survey, 79% of respondents strongly agreed or somewhat agreed that the FDA is responding effectively to advancements in medical technology.', Short\_Summary = 'In its most recent assessment, FDA found almost two-third of manufacturers of novel technology devices plan to bring their products to the U.S. first or in parallel with other major markets. There is still room to improve for FDA, particularly with 33% of respondents viewing its digital product pathway as predictable, but there was broad support for some of its key initiatives and a perception that it now offers a clearer path to market than the EU.In the survey, 79% of respondents strongly agreed or somewhat agreed that the FDA is responding effectively to advancements in medical technology.' WHERE Title = 'US replaces EU as priority market for medtech industry: survey' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'US replaces EU as priority market for medtech industry: survey', 'https://www.medtechdive.com/news/us-replaces-eu-priority-market-medtechs/620450/', '2022-03-16', 'At the same time, FDA has set the target of making the U.S. the priority market for developers of novel devices. In its most recent assessment, FDA found almost two-third of manufacturers of novel technology devices plan to bring their products to the U.S. first or in parallel with other major markets. Only 22% of respondents said the EU pathway for regulatory approval of standard medical technology is predictable. There is still room to improve for FDA, particularly with 33% of respondents viewing its digital product pathway as predictable, but there was broad support for some of its key initiatives and a perception that it now offers a clearer path to market than the EU.In the survey, 79% of respondents strongly agreed or somewhat agreed that the FDA is responding effectively to advancements in medical technology.', 'In its most recent assessment, FDA found almost two-third of manufacturers of novel technology devices plan to bring their products to the U.S. first or in parallel with other major markets. There is still room to improve for FDA, particularly with 33% of respondents viewing its digital product pathway as predictable, but there was broad support for some of its key initiatives and a perception that it now offers a clearer path to market than the EU.In the survey, 79% of respondents strongly agreed or somewhat agreed that the FDA is responding effectively to advancements in medical technology.', 'medtech');

17

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'Steep drop in medical device reports on Bayer''s Essure in 2021, FDA data show') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'Steep drop in medical device reports on Bayer''s Essure in 2021, FDA data show', Article\_URL = 'https://www.medtechdive.com/news/drop-in-device-reports-bayers-essure-2021-fda/620380/', Article\_Published\_Date = '2022-03-15', Keywords = 'device', Long\_Summary = 'While it is now years since Essure was sold in the U.S., the analysis of data on the safety of the device continues apace. The webpage now features details of the agency’s analysis of the medical device reports it received in relation to Essure last year. Bayer submitted 98% of the Essure reports received by the agency last year. The company has been the main source of Essure reports to FDA since 2016.FDA said the "nature and severity of the reports in 2021 remain consistent with prior years."', Short\_Summary = 'The webpage now features details of the agency’s analysis of the medical device reports it received in relation to Essure last year. The company has been the main source of Essure reports to FDA since 2016.FDA said the "nature and severity of the reports in 2021 remain consistent with prior years."' WHERE Title = 'Steep drop in medical device reports on Bayer''s Essure in 2021, FDA data show' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'Steep drop in medical device reports on Bayer''s Essure in 2021, FDA data show', 'https://www.medtechdive.com/news/drop-in-device-reports-bayers-essure-2021-fda/620380/', '2022-03-15', 'While it is now years since Essure was sold in the U.S., the analysis of data on the safety of the device continues apace. The webpage now features details of the agency’s analysis of the medical device reports it received in relation to Essure last year. Bayer submitted 98% of the Essure reports received by the agency last year. The company has been the main source of Essure reports to FDA since 2016.FDA said the "nature and severity of the reports in 2021 remain consistent with prior years."', 'The webpage now features details of the agency’s analysis of the medical device reports it received in relation to Essure last year. The company has been the main source of Essure reports to FDA since 2016.FDA said the "nature and severity of the reports in 2021 remain consistent with prior years."', 'device');

18

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'Apyx''s surgical device gets FDA warning on off-label skin procedure use') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'Apyx''s surgical device gets FDA warning on off-label skin procedure use', Article\_URL = 'https://www.medtechdive.com/news/apyxs-surgical-device-gets-fda-warning-on-off-label-skin-procedure-use/620379/', Article\_Published\_Date = '2022-03-15', Keywords = 'device', Long\_Summary = 'The reports to the agency describe "serious and potentially life-threatening adverse events after the device was used for aesthetic skin procedures." In response, the FDA has told healthcare providers the device is not cleared or approved for any aesthetic skin procedures and off-label use in that context may result in serious and potentially life-threatening adverse events. " Do not use the Renuvion/J-Plasma device for dermal resurfacing or skin contraction, alone or in combination with liposuction," the agency warned healthcare providers. " The number of subdermal coagulation procedures performed with the Apyx products more than doubled from 2020 to 2021.The CEO added that Apyx''s two pending 510(k) premarket notifications remain under review by the FDA, which "are intended to obtain a general indication for use of the Renuvion Dermal handpiece in dermatological procedures requiring ablation and resurfacing of the skin, and a specific clinical indication for treating wrinkles and rhytids."', Short\_Summary = 'The reports to the agency describe "serious and potentially life-threatening adverse events after the device was used for aesthetic skin procedures." In response, the FDA has told healthcare providers the device is not cleared or approved for any aesthetic skin procedures and off-label use in that context may result in serious and potentially life-threatening adverse events. "' WHERE Title = 'Apyx''s surgical device gets FDA warning on off-label skin procedure use' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'Apyx''s surgical device gets FDA warning on off-label skin procedure use', 'https://www.medtechdive.com/news/apyxs-surgical-device-gets-fda-warning-on-off-label-skin-procedure-use/620379/', '2022-03-15', 'The reports to the agency describe "serious and potentially life-threatening adverse events after the device was used for aesthetic skin procedures." In response, the FDA has told healthcare providers the device is not cleared or approved for any aesthetic skin procedures and off-label use in that context may result in serious and potentially life-threatening adverse events. " Do not use the Renuvion/J-Plasma device for dermal resurfacing or skin contraction, alone or in combination with liposuction," the agency warned healthcare providers. " The number of subdermal coagulation procedures performed with the Apyx products more than doubled from 2020 to 2021.The CEO added that Apyx''s two pending 510(k) premarket notifications remain under review by the FDA, which "are intended to obtain a general indication for use of the Renuvion Dermal handpiece in dermatological procedures requiring ablation and resurfacing of the skin, and a specific clinical indication for treating wrinkles and rhytids."', 'The reports to the agency describe "serious and potentially life-threatening adverse events after the device was used for aesthetic skin procedures." In response, the FDA has told healthcare providers the device is not cleared or approved for any aesthetic skin procedures and off-label use in that context may result in serious and potentially life-threatening adverse events. "', 'device');

19

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'FDA orders Philips to notify customers about sleep device recall due to ''inadequate'' prior efforts') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'FDA orders Philips to notify customers about sleep device recall due to ''inadequate'' prior efforts', Article\_URL = 'https://www.medtechdive.com/news/fda-orders-philips-notify-customer-recall/620250/', Article\_Published\_Date = '2022-03-11', Keywords = 'recall | device', Long\_Summary = 'The agency ordered Philips to notify all device users, durable medical equipment suppliers, distributors, retailers and healthcare providers that prescribe the products about the health risks posed by the foam in recalled products. The FDA also ordered Philips to maintain "prominently displayed information" on their main webpage for the recall regarding the risk of using ozone cleaners on the recalled devices, which the company has attributed as one cause of the foam breakdown. "The information currently available on Philips'' website is vague, and does not provide healthcare providers with the facts necessary for them to make informed decisions regarding the risks associated with the continued use of the Recalled Products for their patients," the agency stated in its letter. The financial impact of the recall may grow as Philips faces lawsuits in and outside of the U.S.In its annual report released in February, Philips said that the company faced about 100 class-action lawsuits in the U.S. as of Dec. 31, 2021, that allege "economic loss and/or medical monitoring claims."', Short\_Summary = '"The information currently available on Philips'' website is vague, and does not provide healthcare providers with the facts necessary for them to make informed decisions regarding the risks associated with the continued use of the Recalled Products for their patients," the agency stated in its letter. The financial impact of the recall may grow as Philips faces lawsuits in and outside of the U.S.In its annual report released in February, Philips said that the company faced about 100 class-action lawsuits in the U.S. as of Dec. 31, 2021, that allege "economic loss and/or medical monitoring claims."' WHERE Title = 'FDA orders Philips to notify customers about sleep device recall due to ''inadequate'' prior efforts' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'FDA orders Philips to notify customers about sleep device recall due to ''inadequate'' prior efforts', 'https://www.medtechdive.com/news/fda-orders-philips-notify-customer-recall/620250/', '2022-03-11', 'The agency ordered Philips to notify all device users, durable medical equipment suppliers, distributors, retailers and healthcare providers that prescribe the products about the health risks posed by the foam in recalled products. The FDA also ordered Philips to maintain "prominently displayed information" on their main webpage for the recall regarding the risk of using ozone cleaners on the recalled devices, which the company has attributed as one cause of the foam breakdown. "The information currently available on Philips'' website is vague, and does not provide healthcare providers with the facts necessary for them to make informed decisions regarding the risks associated with the continued use of the Recalled Products for their patients," the agency stated in its letter. The financial impact of the recall may grow as Philips faces lawsuits in and outside of the U.S.In its annual report released in February, Philips said that the company faced about 100 class-action lawsuits in the U.S. as of Dec. 31, 2021, that allege "economic loss and/or medical monitoring claims."', '"The information currently available on Philips'' website is vague, and does not provide healthcare providers with the facts necessary for them to make informed decisions regarding the risks associated with the continued use of the Recalled Products for their patients," the agency stated in its letter. The financial impact of the recall may grow as Philips faces lawsuits in and outside of the U.S.In its annual report released in February, Philips said that the company faced about 100 class-action lawsuits in the U.S. as of Dec. 31, 2021, that allege "economic loss and/or medical monitoring claims."', 'recall | device');

20

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'FDA reaches MDUFA V agreement with industry') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'FDA reaches MDUFA V agreement with industry', Article\_URL = 'https://www.medtechdive.com/news/fda-reaches-mdufa-v-agreement-medical-device/620136/', Article\_Published\_Date = '2022-03-09', Keywords = 'mdufa', Long\_Summary = 'The MDUFA V deal, which determines how much industry pays for FDA product reviews from 2023 to 2027 and what performance goals the agency will be measured against, in the end was about compromise, according to the industry source familiar with the negotiations. "One of the FDA''s priorities that was ultimately included in the MDUFA V agreement was funding for the agency’s proposed total product lifecycle advisory program (TAP), which industry initially opposed. In the MDUFA V agreement, TAP will be funded as a pilot with a MDUFA IV carryover balance of $110 million and an additional $45 million from base funding, according to the industry source, who noted that there will be a pilot mid-point assessment and evaluation during MDUFA VI negotiations. The commitment, which CDRH made in a report on its 2022-2025 strategic priorities, comes as the center''s resources continue to be strained by a COVID-19 workload and follows MDUFA V talks that exposed industry concerns about the number of vacancies at the agency.', Short\_Summary = '"One of the FDA''s priorities that was ultimately included in the MDUFA V agreement was funding for the agency’s proposed total product lifecycle advisory program (TAP), which industry initially opposed. In the MDUFA V agreement, TAP will be funded as a pilot with a MDUFA IV carryover balance of $110 million and an additional $45 million from base funding, according to the industry source, who noted that there will be a pilot mid-point assessment and evaluation during MDUFA VI negotiations.' WHERE Title = 'FDA reaches MDUFA V agreement with industry' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'FDA reaches MDUFA V agreement with industry', 'https://www.medtechdive.com/news/fda-reaches-mdufa-v-agreement-medical-device/620136/', '2022-03-09', 'The MDUFA V deal, which determines how much industry pays for FDA product reviews from 2023 to 2027 and what performance goals the agency will be measured against, in the end was about compromise, according to the industry source familiar with the negotiations. "One of the FDA''s priorities that was ultimately included in the MDUFA V agreement was funding for the agency’s proposed total product lifecycle advisory program (TAP), which industry initially opposed. In the MDUFA V agreement, TAP will be funded as a pilot with a MDUFA IV carryover balance of $110 million and an additional $45 million from base funding, according to the industry source, who noted that there will be a pilot mid-point assessment and evaluation during MDUFA VI negotiations. The commitment, which CDRH made in a report on its 2022-2025 strategic priorities, comes as the center''s resources continue to be strained by a COVID-19 workload and follows MDUFA V talks that exposed industry concerns about the number of vacancies at the agency.', '"One of the FDA''s priorities that was ultimately included in the MDUFA V agreement was funding for the agency’s proposed total product lifecycle advisory program (TAP), which industry initially opposed. In the MDUFA V agreement, TAP will be funded as a pilot with a MDUFA IV carryover balance of $110 million and an additional $45 million from base funding, according to the industry source, who noted that there will be a pilot mid-point assessment and evaluation during MDUFA VI negotiations.', 'mdufa');

21

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'FDA warns of cyber vulnerabilities in medical device software components') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'FDA warns of cyber vulnerabilities in medical device software components', Article\_URL = 'https://www.medtechdive.com/news/fda-cyber-vulnerabilities-PTC-Axeda-medical-device-software-/620075/', Article\_Published\_Date = '2022-03-09', Keywords = 'device | software', Long\_Summary = 'All versions of PTC''s Axeda agent and desktop server are affected by the Access:7 cyber vulnerabilities, according to FDA''s alert to device users and manufacturers. Axel Wirth, chief security strategist of medical device cyber firm MedCrypt, called it "astounding" that nine years after CISA issued one of its early cybersecurity alerts calling out the risk of hard-coded passwords, the medtech industry is still seeing advisories that are related to hard-coded credentials. Becton Dickinson on Tuesday in a statement said it is "aware of and actively monitoring" vulnerabilities associated with PTC''s Axeda agent and desktop server, which are no longer used in BD''s products. BD voluntarily reported the vulnerabilities to CISA and the FDA.CISA last week issued two separate advisories warning that successful exploitation of BD''s Viper hard-coded credential vulnerability "could allow an attacker to access, modify, or delete sensitive information," while the company''s Pyxis hard-coded credential vulnerability "could allow an attacker to gain access to electronic protected health information (ePHI) or other sensitive information."', Short\_Summary = 'All versions of PTC''s Axeda agent and desktop server are affected by the Access:7 cyber vulnerabilities, according to FDA''s alert to device users and manufacturers. Becton Dickinson on Tuesday in a statement said it is "aware of and actively monitoring" vulnerabilities associated with PTC''s Axeda agent and desktop server, which are no longer used in BD''s products.' WHERE Title = 'FDA warns of cyber vulnerabilities in medical device software components' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'FDA warns of cyber vulnerabilities in medical device software components', 'https://www.medtechdive.com/news/fda-cyber-vulnerabilities-PTC-Axeda-medical-device-software-/620075/', '2022-03-09', 'All versions of PTC''s Axeda agent and desktop server are affected by the Access:7 cyber vulnerabilities, according to FDA''s alert to device users and manufacturers. Axel Wirth, chief security strategist of medical device cyber firm MedCrypt, called it "astounding" that nine years after CISA issued one of its early cybersecurity alerts calling out the risk of hard-coded passwords, the medtech industry is still seeing advisories that are related to hard-coded credentials. Becton Dickinson on Tuesday in a statement said it is "aware of and actively monitoring" vulnerabilities associated with PTC''s Axeda agent and desktop server, which are no longer used in BD''s products. BD voluntarily reported the vulnerabilities to CISA and the FDA.CISA last week issued two separate advisories warning that successful exploitation of BD''s Viper hard-coded credential vulnerability "could allow an attacker to access, modify, or delete sensitive information," while the company''s Pyxis hard-coded credential vulnerability "could allow an attacker to gain access to electronic protected health information (ePHI) or other sensitive information."', 'All versions of PTC''s Axeda agent and desktop server are affected by the Access:7 cyber vulnerabilities, according to FDA''s alert to device users and manufacturers. Becton Dickinson on Tuesday in a statement said it is "aware of and actively monitoring" vulnerabilities associated with PTC''s Axeda agent and desktop server, which are no longer used in BD''s products.', 'device | software');

22

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'Medtronic, Nevro boosted by expansion of Medicare coverage for diabetic pain devices') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.medtechdive.com/topic/medical-devices/', Title = 'Medtronic, Nevro boosted by expansion of Medicare coverage for diabetic pain devices', Article\_URL = 'https://www.medtechdive.com/news/medtronic-nevro-boosted-by-expansion-of-medicare-coverage-for-diabetic-pai/620076/', Article\_Published\_Date = '2022-03-09', Keywords = 'device', Long\_Summary = 'Nevro said the Noridian update covers around 8% of PDN patients in the U.S.Working to capture what management sees as an "important driver" of long-term growth, Nevro needs to grow coverage of SCS in PDN to kickstart its business. "Noridian''s update is not exclusive to any one waveform or frequency but rather based on the overall body of evidence which supports SCS as a treatment option for these patients," a Medtronic spokesperson said in an emailed statement. " We will continue to engage with outstanding Medicare contractors and private payers to share existing clinical evidence to encourage the addition of diabetic peripheral neuropathy to their coverage policies where needed," Nevro put a positive spin on Medtronic''s FDA approval, with CEO Keith Grossman using a conference call to discuss fourth quarter results to argue "having a second market participant raising awareness about this indication with referring doctors and patients can only be helpful in developing the referral channel and in accelerating market expansion." We expect to have announcements like this throughout the year as we continue our activities to expand payer outreach to include spinal cord stimulation coverage for peripheral diabetic neuropathy," a spokesperson for Nevro said. "', Short\_Summary = 'Nevro said the Noridian update covers around 8% of PDN patients in the U.S.Working to capture what management sees as an "important driver" of long-term growth, Nevro needs to grow coverage of SCS in PDN to kickstart its business. 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WHERE Title = 'Medtronic, Nevro boosted by expansion of Medicare coverage for diabetic pain devices' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.medtechdive.com/topic/medical-devices/', 'Medtronic, Nevro boosted by expansion of Medicare coverage for diabetic pain devices', 'https://www.medtechdive.com/news/medtronic-nevro-boosted-by-expansion-of-medicare-coverage-for-diabetic-pai/620076/', '2022-03-09', 'Nevro said the Noridian update covers around 8% of PDN patients in the U.S.Working to capture what management sees as an "important driver" of long-term growth, Nevro needs to grow coverage of SCS in PDN to kickstart its business. "Noridian''s update is not exclusive to any one waveform or frequency but rather based on the overall body of evidence which supports SCS as a treatment option for these patients," a Medtronic spokesperson said in an emailed statement. 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"', 'Nevro said the Noridian update covers around 8% of PDN patients in the U.S.Working to capture what management sees as an "important driver" of long-term growth, Nevro needs to grow coverage of SCS in PDN to kickstart its business. We will continue to engage with outstanding Medicare contractors and private payers to share existing clinical evidence to encourage the addition of diabetic peripheral neuropathy to their coverage policies where needed," Nevro put a positive spin on Medtronic''s FDA approval, with CEO Keith Grossman using a conference call to discuss fourth quarter results to argue "having a second market participant raising awareness about this indication with referring doctors and patients can only be helpful in developing the referral channel and in accelerating market expansion."', 'device');

23

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'shuren apologizes for mdufa delay, says fda will start closing the spigot on new euas') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.raps.org/news-and-articles/news-articles', Title = 'shuren apologizes for mdufa delay, says fda will start closing the spigot on new euas', Article\_URL = 'https://www.raps.org/news-and-articles/news-articles/2022/3/shuren-apologizes-for-mdufa-delay-says-fda-will-st', Article\_Published\_Date = '2022-03-30', Keywords = 'mdufa', Long\_Summary = 'At the start of the meeting committee Chair Frank Pallone (D-NJ) and Ranking Member Cathy McMorris Rodgers (R-OR), scolded Jeff Shuren, director of the Center for Devices and Radiological Health (CDRH), for missing the 15 January deadline to submit a MDUFA V commitment letter. ( RELATED: MDUFA V: Commitment letter includes TPLC pilot, claw back provisions and more, Regulatory Focus 23 March 2022) The letter is a tentative deal between FDA and the medtech industry on how much revenue the agency will bring in over the next five years to help pay for reviewing premarket applications while also setting performance goals for reviewers to meet. “ McMorris Rodgers pushed on the fact FDA hasn’t provided meeting minutes on negotiations between itself and industry since 30 June and asked Shuren how many meetings have been held since. During the hearing McMorris Rodgers noted that FDA published two draft guidances in December on transitioning EUA products to regular marketing authorization.', Short\_Summary = 'At the start of the meeting committee Chair Frank Pallone (D-NJ) and Ranking Member Cathy McMorris Rodgers (R-OR), scolded Jeff Shuren, director of the Center for Devices and Radiological Health (CDRH), for missing the 15 January deadline to submit a MDUFA V commitment letter. ( RELATED: MDUFA V: Commitment letter includes TPLC pilot, claw back provisions and more, Regulatory Focus 23 March 2022) The letter is a tentative deal between FDA and the medtech industry on how much revenue the agency will bring in over the next five years to help pay for reviewing premarket applications while also setting performance goals for reviewers to meet. “' WHERE Title = 'shuren apologizes for mdufa delay, says fda will start closing the spigot on new euas' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.raps.org/news-and-articles/news-articles', 'shuren apologizes for mdufa delay, says fda will start closing the spigot on new euas', 'https://www.raps.org/news-and-articles/news-articles/2022/3/shuren-apologizes-for-mdufa-delay-says-fda-will-st', '2022-03-30', 'At the start of the meeting committee Chair Frank Pallone (D-NJ) and Ranking Member Cathy McMorris Rodgers (R-OR), scolded Jeff Shuren, director of the Center for Devices and Radiological Health (CDRH), for missing the 15 January deadline to submit a MDUFA V commitment letter. ( RELATED: MDUFA V: Commitment letter includes TPLC pilot, claw back provisions and more, Regulatory Focus 23 March 2022) The letter is a tentative deal between FDA and the medtech industry on how much revenue the agency will bring in over the next five years to help pay for reviewing premarket applications while also setting performance goals for reviewers to meet. “ McMorris Rodgers pushed on the fact FDA hasn’t provided meeting minutes on negotiations between itself and industry since 30 June and asked Shuren how many meetings have been held since. During the hearing McMorris Rodgers noted that FDA published two draft guidances in December on transitioning EUA products to regular marketing authorization.', 'At the start of the meeting committee Chair Frank Pallone (D-NJ) and Ranking Member Cathy McMorris Rodgers (R-OR), scolded Jeff Shuren, director of the Center for Devices and Radiological Health (CDRH), for missing the 15 January deadline to submit a MDUFA V commitment letter. ( RELATED: MDUFA V: Commitment letter includes TPLC pilot, claw back provisions and more, Regulatory Focus 23 March 2022) The letter is a tentative deal between FDA and the medtech industry on how much revenue the agency will bring in over the next five years to help pay for reviewing premarket applications while also setting performance goals for reviewers to meet. “', 'mdufa');

24

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'fda approvals roundup: pluvicto, cabenuva, fintepla') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.raps.org/news-and-articles/news-articles', Title = 'fda approvals roundup: pluvicto, cabenuva, fintepla', Article\_URL = 'https://www.raps.org/news-and-articles/news-articles/2022/3/fda-approvals-roundup-pluvicto-cabenuva-fintepla', Article\_Published\_Date = '2022-03-30', Keywords = 'approval', Long\_Summary = 'Approval of Pluvicto was based on findings from the multicenter, open label VISION trial in which patients from the indicated population were randomized 2:1 to receive Pluvicto plus best standard of care (BSoC; 551 patients) or BSoC alone (280 patients). New indications Cabenuva HIV regimen nabs expanded indication for adolescents ViiV Healthcare’s Cabenuva (cabotegravir and rilpivirine) has been granted a new indication for treating HIV-1 in virologically suppressed patients aged 12 years or older. Approval for the expanded indication was supported by efficacy findings extrapolated from adults with support from pharmacokinetic analyses showing similar drug exposure and from safety data from the week 16 interim analysis of the ongoing MOCHA study in 23 patients from the indicated population. Fintepla okayed for seizures associated with Lennox-Gastaut syndrome UCB’s Fintepla (fenfluramine; oral solution) has been granted a new indication for treating seizures associated with Lennox-Gastaut syndrome in patients aged 2 years or older.', Short\_Summary = 'New indications Cabenuva HIV regimen nabs expanded indication for adolescents ViiV Healthcare’s Cabenuva (cabotegravir and rilpivirine) has been granted a new indication for treating HIV-1 in virologically suppressed patients aged 12 years or older. Fintepla okayed for seizures associated with Lennox-Gastaut syndrome UCB’s Fintepla (fenfluramine; oral solution) has been granted a new indication for treating seizures associated with Lennox-Gastaut syndrome in patients aged 2 years or older.' WHERE Title = 'fda approvals roundup: pluvicto, cabenuva, fintepla' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.raps.org/news-and-articles/news-articles', 'fda approvals roundup: pluvicto, cabenuva, fintepla', 'https://www.raps.org/news-and-articles/news-articles/2022/3/fda-approvals-roundup-pluvicto-cabenuva-fintepla', '2022-03-30', 'Approval of Pluvicto was based on findings from the multicenter, open label VISION trial in which patients from the indicated population were randomized 2:1 to receive Pluvicto plus best standard of care (BSoC; 551 patients) or BSoC alone (280 patients). New indications Cabenuva HIV regimen nabs expanded indication for adolescents ViiV Healthcare’s Cabenuva (cabotegravir and rilpivirine) has been granted a new indication for treating HIV-1 in virologically suppressed patients aged 12 years or older. Approval for the expanded indication was supported by efficacy findings extrapolated from adults with support from pharmacokinetic analyses showing similar drug exposure and from safety data from the week 16 interim analysis of the ongoing MOCHA study in 23 patients from the indicated population. Fintepla okayed for seizures associated with Lennox-Gastaut syndrome UCB’s Fintepla (fenfluramine; oral solution) has been granted a new indication for treating seizures associated with Lennox-Gastaut syndrome in patients aged 2 years or older.', 'New indications Cabenuva HIV regimen nabs expanded indication for adolescents ViiV Healthcare’s Cabenuva (cabotegravir and rilpivirine) has been granted a new indication for treating HIV-1 in virologically suppressed patients aged 12 years or older. Fintepla okayed for seizures associated with Lennox-Gastaut syndrome UCB’s Fintepla (fenfluramine; oral solution) has been granted a new indication for treating seizures associated with Lennox-Gastaut syndrome in patients aged 2 years or older.', 'approval');

25

IF EXISTS (SELECT \* FROM [ais\_poc].[Article\_Details] WHERE Title = 'asia-pacific roundup: philippine fda seeks feedback on expedited evaluation of medical devices') UPDATE [ais\_poc].[Article\_Details] SET Identifier = 'https://www.raps.org/news-and-articles/news-articles', Title = 'asia-pacific roundup: philippine fda seeks feedback on expedited evaluation of medical devices', Article\_URL = 'https://www.raps.org/news-and-articles/news-articles/2022/3/asia-pacific-roundup-philippine-fda-seeks-feedback', Article\_Published\_Date = '2022-03-29', Keywords = 'medical devices | device', Long\_Summary = 'The technical requirements to be submitted shall be the same as those submitted to the reference NRA of the ASEAN member country where the Certificate of Product Registration (CPR) was issued,” the guidelines state. TGA Notice China’s NMPA posts guidance on self-inspection of device quality systems China’s National Medical Products Administration (NMPA) has updated its guidance on the annual self-inspection of medical device quality management systems as part of a raft of changes that will take effect on 1 May. The updated guideline is one of three new or updated documents that NMPA will implement in a little over one month. NMPA Notice (Chinese) India approves Novavax’s COVID vaccine for use in adolescents The Drugs Controller General of India (DCGI) has granted emergency use authorization (EUA) to Novavax’s COVID-19 vaccine in adolescents aged 12 to 18 years. Press Release China’s NMPA prepares for WHO assessment of vaccine regulatory capacity China’s NMPA has held a meeting in preparation for a national regulatory authority (NRA) assessment of vaccines by the World Health Organization (WHO).', Short\_Summary = 'NMPA Notice (Chinese) India approves Novavax’s COVID vaccine for use in adolescents The Drugs Controller General of India (DCGI) has granted emergency use authorization (EUA) to Novavax’s COVID-19 vaccine in adolescents aged 12 to 18 years. Press Release China’s NMPA prepares for WHO assessment of vaccine regulatory capacity China’s NMPA has held a meeting in preparation for a national regulatory authority (NRA) assessment of vaccines by the World Health Organization (WHO).' WHERE Title = 'asia-pacific roundup: philippine fda seeks feedback on expedited evaluation of medical devices' ELSE INSERT INTO [ais\_poc].[Article\_Details] (Identifier, Title, Article\_URL, Article\_Published\_Date, Long\_Summary, Short\_Summary, Keywords) VALUES ('https://www.raps.org/news-and-articles/news-articles', 'asia-pacific roundup: philippine fda seeks feedback on expedited evaluation of medical devices', 'https://www.raps.org/news-and-articles/news-articles/2022/3/asia-pacific-roundup-philippine-fda-seeks-feedback', '2022-03-29', 'The technical requirements to be submitted shall be the same as those submitted to the reference NRA of the ASEAN member country where the Certificate of Product Registration (CPR) was issued,” the guidelines state. TGA Notice China’s NMPA posts guidance on self-inspection of device quality systems China’s National Medical Products Administration (NMPA) has updated its guidance on the annual self-inspection of medical device quality management systems as part of a raft of changes that will take effect on 1 May. The updated guideline is one of three new or updated documents that NMPA will implement in a little over one month. NMPA Notice (Chinese) India approves Novavax’s COVID vaccine for use in adolescents The Drugs Controller General of India (DCGI) has granted emergency use authorization (EUA) to Novavax’s COVID-19 vaccine in adolescents aged 12 to 18 years. Press Release China’s NMPA prepares for WHO assessment of vaccine regulatory capacity China’s NMPA has held a meeting in preparation for a national regulatory authority (NRA) assessment of vaccines by the World Health Organization (WHO).', 'NMPA Notice (Chinese) India approves Novavax’s COVID vaccine for use in adolescents The Drugs Controller General of India (DCGI) has granted emergency use authorization (EUA) to Novavax’s COVID-19 vaccine in adolescents aged 12 to 18 years. Press Release China’s NMPA prepares for WHO assessment of vaccine regulatory capacity China’s NMPA has held a meeting in preparation for a national regulatory authority (NRA) assessment of vaccines by the World Health Organization (WHO).', 'medical devices | device');

In [12]:

cursor.execute(query\_count)

for row in cursor:

print(row)

(59, )