

Pancreas medical device recall



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Introduction

Previous Research

- Medical errors, the third leading cause of death in the United States, underscore the importance of prioritizing human factors (Liebel et al., 2018)
- There is an urgent need to regulatory reform to ensure medical device safety. (Zuckerman et al., 2011)
- Despite its importance, little research exists on the factors influencing device recalls decision (Ball et al., 2018)

We need to understand the reason behind pancreas device recalls before we solve above issues.

Introduction

Why is pancreas important?

- The pancreas holds a vital role in our well-being. So do the devices designed to support it (Vallis, 2016)
- We expect pancreas medical devices are reliable, but the recall rate of medical device is among the top (Zhou et al., 2022)
- This question holds the key to improving patient safety, elevating healthcare quality, and reducing unforeseen disruptions.

What factors contribute to the recall of a pancreas medical device?

Data To Collect

- Number Of Devices Recalled
- Recall Date
- Company
- Devices distribution
- Issue with device (e.g. Faulty design, Software, Manufacturing)

How scalable

Patient-Centric Studies:

- Patient impact
- Recalled vs. non-recalled devices

Technological Innovations:

- Emerging technologies

Post-Market Surveillance:

- The current post-market surveillance systems
- Machine learning or artificial intelligence

Scraping FDA Data from OpenFDA

Data Source

The data for this project is sourced from the OpenFDA API. The OpenFDA API is an Elasticsearch-based platform that serves public FDA data about drugs, devices, and foods. The focus is on the Device Recall dataset.

Tools and Technologies

Python is used for programmatically sending requests. Libraries such as BeautifulSoup and requests are used for data collection.

- + Animal & Veterinary API Endpoints
- + Drug API Endpoints
- Device API Endpoints
 - + 510(k)
 - + Classification
 - + Recall Enforcement Reports
 - + Adverse Events
 - + Pre-market Approval
 - + Recalls
 - + Registrations and Listings
 - + COVID-19 Serological Testing Evaluations
 - + Unique Device Identifier
- + Food API Endpoints
- + Other API Endpoints
- + Tobacco API Endpoints

Scraping FDA Data from OpenFDA

Scraping Process

API calls were manually conducted to explore the structure of the data and understand the parameters available for querying.

Initial exploration of the OpenFDA API using a web browser.

Example of a sample API call to the Device Recall endpoint:

https://api.fda.gov/device/recall.json?search=product_description:'Pancreas'&limit=5

Data Retrieval and Structure

The OpenFDA API returns individual results as JSON objects.

The JSON objects comprise two main sections: meta and results.

The structure of the JSON response facilitates efficient extraction and subsequent analysis of the data.

-

api.fda.gov/device/recall.json?search=product_description:"Pancreas"

```
{
  "meta": {
    "disclaimer": "Do not rely on openFDA to make decisions regarding medical care. While we make every effort to ensure that data is",
    "terms": "https://open.fda.gov/terms/",
    "license": "https://open.fda.gov/license/",
    "last_updated": "2023-12-01",
    "results": {
      "skip": 0,
      "limit": 1,
      "total": 24
    }
  },
  "results": [
    {
      "cfres_id": "149666",
      "product_res_number": "Z-0123-2017",
      "event_date_initiated": "2016-08-02",
      "event_date_posted": "2016-10-18",
      "recall_status": "Terminated",
      "event_date_terminated": "2017-09-07",
      "res_event_number": "75207",
      "product_code": "CDT",
      "k_numbers": [
        "K020238"
      ],
      "product_description": "Randox Lipase (Colorimetric)\n\nProduct Usage:\nA lipase test system is a device intended to measure the",
      "code_info": "Catalogue number: LI3837, LI7979, LI8050, LI8361",
      "recalling_firm": "Randox Laboratories Ltd.\n55 Diamond Road\nCrumlin (North) Ireland",
      "reason_for_recall": "According to the firm carry over was observed when the Lipase test is run directly before or after the LDI",
      "root_cause_description": "Nonconforming Material/Component",
      "action": "Randex Laboratories sent an Urgent Field Safety Notice letter dated June 17, 2016 to affected customers. The letter",
      "product_quantity": "18",
      "distribution_status": "US Nationwide Distribution"
```

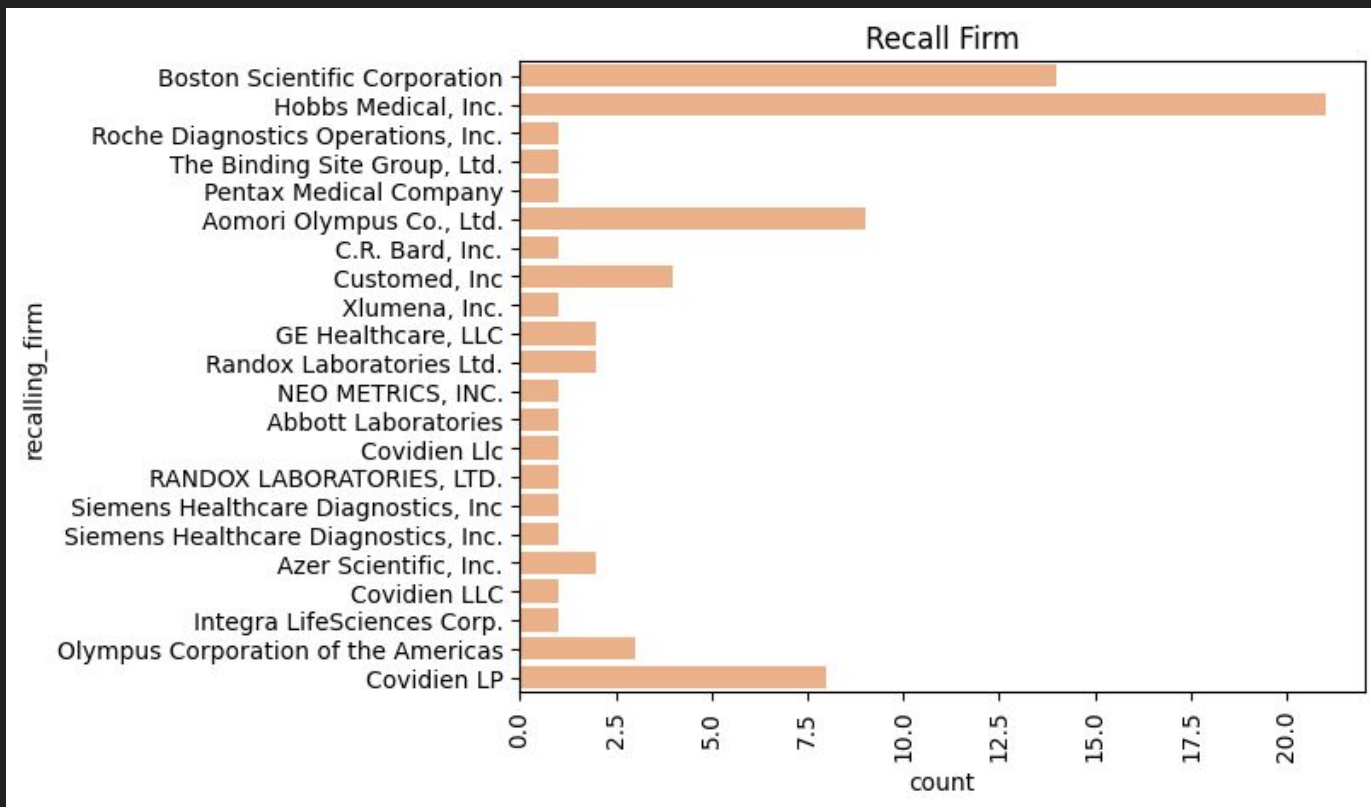
Dirty Data

| action | addition | address | address | cfres_id | city | device_c | device_n | distribut | event_d | event_d | event_d | fe_i | numl_k | numbe_k | numbe_k | medical | postal_c | product | product | product | product | reason | recall | recall | registrat | regulatio | res_ever | root_cau | state |
|--------------------|------------------|---------------------|----------|------------------|------|------------|------------|-----------|---------|---------|---------|------------|------------|------------|----------------|------------|-------------|-----------------|------------|------------|-------------|------------|------------|--------------|------------|-----------|----------|----------|-------|
| The On | 800-437-7990 | Innovation D | 202850 | Wauwat | 2 | Compute | Distribu | ##### | ##### | ##### | ##### | ['301325C | ['K082467 | ['K213972 | Cardiova | 53226-48 | DQK | Prucka 3 | 81 ampli | Z-2613-2Z | A diode | (GE Medi | Open, Cl | ['301325C | 870.143 | 92903 | Compon | WI | |
| Philips | | | 202893 | | 2 | Monitor, | US-AZ, | ##### | ##### | ##### | ##### | ['300383Z | ['K042642 | ['K20174E | Cardiovascular | MXH | Philips | 5773 | Z-2625-2Z | Full scre | Remote | (Open, Cl | ['303115E | 870.103 | 92914 | Device | Design | | |
| Stryker | same | 1941 Stryker Way | 202688 | Portage | 2 | Cement | (Nation | ##### | ##### | ##### | ##### | ['300021S | ['K95193C | ['K931847 | General, | 49002-97 | LZN | Stryker | 16 units | Z-2601-2Z | Potentia | Stryker C | Open, Cl | ['264866E | 878.33 | 92841 | Under | In MI | |
| Ambu | SAME | 6721 Colt Ste 200 | 202813 | Columbi | 1 | Accesso | Nationw | ##### | ##### | ##### | ##### | ['300509E | ['K940152 | ['K81254 | Gastroer | 21046-33 | FEM | Ambu | 2689 unit | Z-2628-2Z | Multiple | Ambu In | Open, Cl | ['300509E | 876.15 | 92886 | Device | D MD | |
| The firm | 747-242-22617 | Mariano St | 196079 | Woodlar N | 1 | Uv Lamp, | US Natio | ##### | ##### | ##### | ##### | Unknown | 91367-61 | RHP | The prod | 485 units | Z-0003-2Z | Excessive | IN MY | BA Open, | Classified | | | | 90860 | Radiatio | CA | | |
| A CryoLif | Connie | 1655 Roberts Blvd | 26121 | Kennesa | 3 | Heart-Va | One unit | ##### | ##### | ##### | ##### | Unknown | 30144 | MIE | CryoValv | 1 unit | Z-0076-0Z | An alloq | Cryolife | I | Terminated | | | | 25995 | Other | GA | | |
| Consignee | was nc | 1714 Hayes Street | 25925 | Nashvilli | 3 | Heart-Va | GA | ##### | ##### | ##### | ##### | Unknown | 37203 | MIE | One hea | One hea | Z-0677-0Z | Human t | DCI Donc | Terminated | | | | 25493 | Other | TN | | | |
| Field modification | 3000 N Grandview | 25985 | Waukesha | | | The prod | ##### | ##### | ##### | ##### | ##### | ['K012389 | | | 53186 | 90LMA | Revoluti | 78 device | Z-0157-0Z | The devi | General | Terminated | | | 25531 | Other | WI | | |
| Urgent d | 800-521-6200 | Jackson Rd. | 29050 | Ann Arbor | | United S | ##### | ##### | ##### | ##### | ##### | ['K915193A | | | 48103 | 74DWF | Sarns brand | Retro Z-1191-0Z | Product i | Terumo | (Terminated | | | | 27041 | Other | MI | | |
| Urgent d | 800-521-6200 | Jackson Rd. | 29051 | Ann Arbor | | United S | ##### | ##### | ##### | ##### | ##### | ['K925442 | | | 48103 | 74DWF | Sarns brand | Retro Z-1192-0Z | Product i | Terumo | (Terminated | | | | 27041 | Other | MI | | |
| Urgent d | 800-521-6200 | Jackson Rd. | 29052 | Ann Arbor | | United S | ##### | ##### | ##### | ##### | ##### | ['K925442 | | | 48103 | 74DWF | Sarns brand | Retro Z-1193-0Z | Product i | Terumo | (Terminated | | | | 27041 | Other | MI | | |
| The phys | Sylvie L. | 1655 Roberts Blvd | 29085 | Kennesa | 3 | Heart-Va | Tissu w | ##### | ##### | ##### | ##### | Unknown | 30144 | MIE | CryoValv | 1 unit | Z-0019-0Z | The hear | Cryolife | I | Terminated | | | | 27051 | Other | GA | | |
| The firm | Chris | 1641 Edlich Dr | 29644 | Charlottesville | | Product v | ##### | ##### | ##### | ##### | ##### | | 22911 | | Wire Drii | 135 | Z-0043-0Z | Wiring p | Microair | I | Terminated | | | | 27301 | Other | VA | | |
| Baxter se | Center | 120 & Wilson Rd | 31080 | Round Lake | | The prod | ##### | ##### | ##### | ##### | ##### | ['K002679 | | | 60073 | FRN-- | Baxter 6C | 188 units | Z-0376-0Z | Prematur | Baxter H | I | Terminated | | | 28037 | Other | IL | |
| The cons | Mr. P. | 1655 Roberts Blvd | 31625 | Kennesa | 3 | Heart-Va | The alloq | ##### | ##### | ##### | ##### | Unknown | 30144-36 | MIE | CryoValv | 1 unit | Z-0548-0Z | As part o | Cryolife | I | Terminated | | | | 28345 | Other | GA | | |
| The reca | Roland | 51 Valley Stream F | 40241 | Malvern | | Nationw | ##### | ##### | ##### | ##### | ##### | | 19355-1406 | | Mammor | 31 units | Z-1045-0Z | potentia | Siemens | Terminated | | | | 32515 | Other | PA | | | |
| The firm | Curtis | 650 Liberty Ave | 44484 | Union f | | Pulmonoi | The devi | ##### | ##### | ##### | ##### | ['2025587 | | | Unknown | 07083-81 | MWH | Shelhigh | 25 units | Z-0678-0Z | Unappro | Shelhigh | Terminat | ['2025587 | | 34692 | Other | NJ | |
| Bard Elei | Chris O. | 129 Concord Road | 25880 | Billerica | | Nationw | ##### | ##### | ##### | ##### | ##### | | 1821 | | Bard | 12 units | Z-0603-0Z | Sterile b | C. R. Bard | Terminated | | | | 25401 | Packagin | MA | | | |
| Consignees | notifi | 604 Queensbury A | 25805 | Queensbury | | There wa | ##### | ##### | ##### | ##### | ##### | ['K000825 | | | 12804 | | JOGRAPH | 50 cathet | Z-0593-0Z | 6 Fr. cath | Jomed C | I | Terminated | | 25424 | Other | NY | | |
| The reca | Gene | 121 Freeport Rd | 25718 | Pittsburgh | | The devi | ##### | ##### | ##### | ##### | ##### | | 1.5E+08 | | Life Vest | 174 units | Z-0578-0Z | Wires m | Lifecor | I | Terminated | | | | 25387 | Other | PA | | |
| A letter c | 425-497- | 6675 185 Suite 10C | 26199 | Redmon | 3 | Columns | ##### | ##### | ##### | ##### | ##### | ['301901E | ['K831423 | | Unknown | 98052 | LQQ | Prosorba | 19 cases | Z-1086-0Z | No packe | Freseniu | Terminat | ['301901E592 | | 26700 | Other | WA | |
| The reca | Roland | 51 Valley Stream F | 26730 | Malvern | | The prod | ##### | ##### | ##### | ##### | ##### | ['K9355694 | | | 19355 | | Magic Vi | 49 units | Z-1029-0Z | software | Siemens | Terminated | | | 25928 | Other | PA | | |
| Customer | 812-934- | 125 E Pearl St | 27937 | Batesville | | United S | ##### | ##### | ##### | ##### | ##### | | 47006 | | Hill-Rom | 1,400 | Z-1028-0Z | The cast | Hill-Rom | Terminated | | | | 26586 | Other | IN | | | |
| Marketir | 877-229- | 1884 Miles Ave. | 27494 | Elkhart | | United S | ##### | ##### | ##### | ##### | ##### | ['K960546 | | | 46515 | | Clinitek | 1324 | Z-0911-0Z | Analyzer | Bayer H | I | Terminated | | 26312 | Other | IN | | |
| Firm con | Melissa | 1430 West McCoy I | 28148 | Santa Maria | | Nationw | ##### | ##### | ##### | ##### | ##### | | 93455 | | Blood Ag | 11,250 pl | Z-1076-0Z | Custom | Hardy M | I | Terminated | | | | 26681 | Other | CA | | |
| On 7/17/ | 425-487- | 22100 Bothell Ever | 28537 | Bothell | | The firm | ##### | ##### | ##### | ##### | ##### | ['K982993 | | | 98041 | | OmnDia | 52 | Z-0874-0Z | Labeling | Philips M | I | Terminated | | 26837 | Other | WA | | |
| The phys | Mr. P. | 1655 Roberts Blvd | 35342 | Kennesa | 3 | Heart-Va | The tiss | ##### | ##### | ##### | ##### | Unknown | 30144-36 | MIE | CryoValv | 1 tissue | Z-0026-0Z | A pre-im | Cryolife | I | Terminated | | | | 30191 | Other | GA | | |
| Smiths S | Timothy | 10 Bowman Dr | 36257 | Keene | | FL | ##### | ##### | ##### | ##### | ##### | | 03431-5043 | | Custom | 357 case | Z-0463-0Z | Mislabel | Smiths M | I | Terminated | | | | 30642 | Other | NH | | |
| Firm sen | Paul | 2441 Michelle Dr | 37400 | Tustin | | Nationw | ##### | ##### | ##### | ##### | ##### | | 92781 | rad | X-Ray Hig | 494 | Z-0494-0Z | Non-com | Toshiba | Terminated | | | | 31217 | Other | CA | | | |
| Own nan | 800-526- | 9115 Hague Rd | 36299 | Indianapolis | | Nationw | ##### | ##### | ##### | ##### | ##### | ['K932642 | ['K97267 | 46256-1025 | | Unknown | 30144-36 | MIE | CryoValv | 1 tissue | Z-0685-0Z | During a | Cryolife | I | Terminated | | 30664 | Other | IN |
| Consigne | Mr. P. | 1655 Roberts Blvd | 37235 | Kennesa | 3 | Heart-Va | CA, NJ, TX | ##### | ##### | ##### | ##### | Unknown | 30144-36 | MIE | CryoValv | 1 tissue | Z-0685-0Z | During a | Cryolife | I | Terminated | | | | 31140 | Other | GA | | |
| The reca | Denis | 340 E Ma Ste 204c | 37581 | Langhorne | | The prod | ##### | ##### | ##### | ##### | ##### | | 19047-2848 | | Uterine | 1115 units | Z-0027-0Z | product i | Bioteque | Terminated | | | | 31276 | Other | PA | | | |
| 1 Fanligh | Linda | 14145 Prt Ste 14 | 46377 | City Of Industry | | Nationw | ##### | ##### | ##### | ##### | ##### | | 91746-28 | U28 | PlusRite | 100,000 t | Z-0454-0Z | These nc | Fanlight | Terminated | | | | 35548 | Other | CA | | | |
| Consigne | 734-487- | 5449 Research Dr | 46267 | Canton | | Worldwi | ##### | ##### | ##### | ##### | ##### | ['K992002 | | | 48188-22 | CCH | Liquid At | To be de | Z-1454-0Z | Unexpec | Pointe S | I | Terminated | | 35497 | Other | MI | | |
| Boston S | Robert | 1 Boston Scientific | 25917 | Natick | | Nationw | ##### | ##### | ##### | ##### | ##### | ['K970052 | | | 1760 | | Boston | 22 units | Z-0551-0Z | Breach i | Boston S | I | Terminated | | 25487 | Other | MA | | |
| The firm | began to | 8200 Car Ste C-140 | 25088 | Austin | | AL, AZ, NI | ##### | ##### | ##### | ##### | ##### | | 78754-38 | --- | Ascensi | Unknown | Z-0549-0Z | Brochure | Ascensi | Terminated | | | | 25056 | Other | TX | | | |
| Implanti | Shari L. | 1655 Roberts Blvd | 27260 | Kennesa | 3 | Heart-Va | The comj | ##### | ##### | ##### | ##### | Unknown | 30144 | MIE | CryoValv | 8 units | Z-0866-0Z | Microorg | Cryolife | I | Terminated | | | | 26205 | Other | GA | | |
| On 3/25/ | Troy | 1602 4th Ave | 26558 | North Billings | | The firm | ##### | ##### | ##### | ##### | ##### | | 59101 | | RJ T&A Pj | 20 | Z-0754-0Z | Product f | Windsto | Terminated | | | | 25830 | Other | MT | | | |
| On 3/25/ | Troy | 1602 4th Ave | 26560 | North Billings | | The firm | ##### | ##### | ##### | ##### | ##### | | 59101 | | BACK PAC | 42 | Z-0756-0Z | Product f | Windsto | Terminated | | | | 25830 | Other | MT | | | |
| Consigne | Sylvie L. | 1655 Roberts Blvd | 30303 | Kennesa | 3 | Heart-Va | The tiss | ##### | ##### | ##### | ##### | Unknown | 30144-36 | MIE | CryoValv | One unit | Z-0167-0Z | CryoLife | I | Cryolife | I | Terminated | | | 27664 | Other | GA | | |

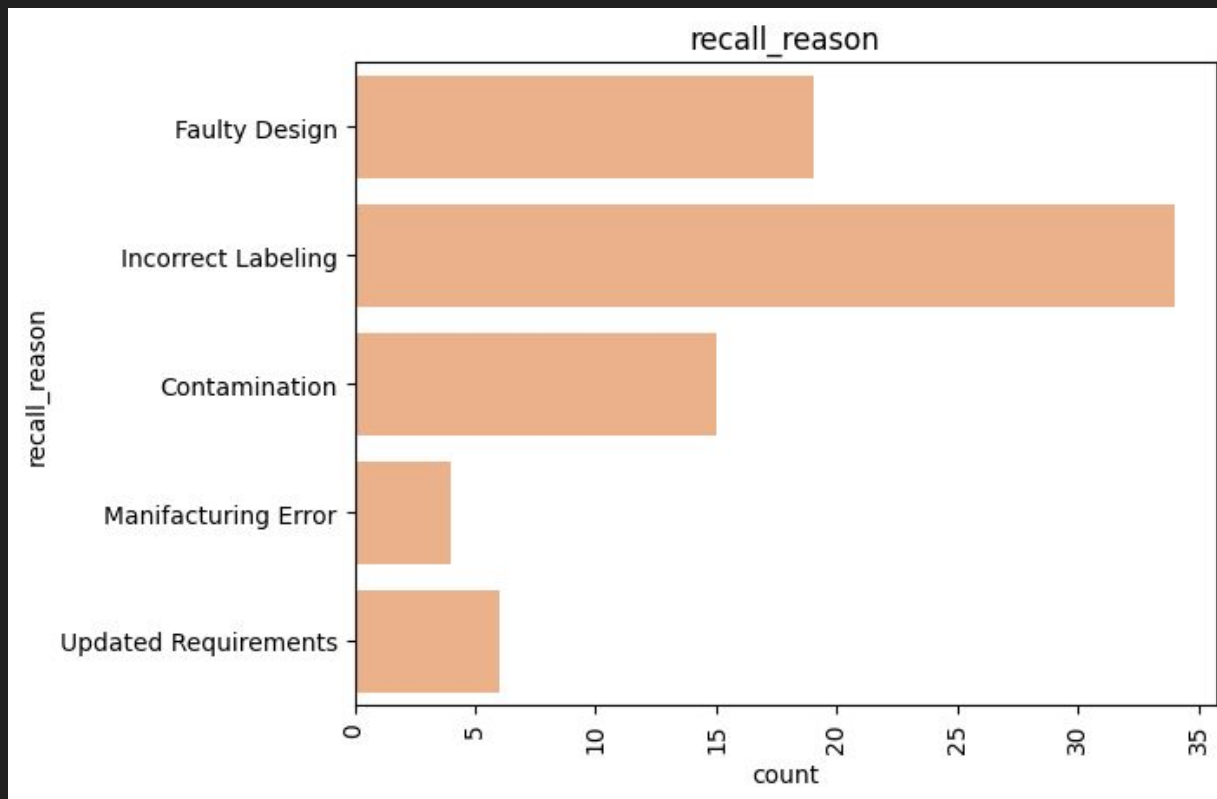
Clean Data

| status | city | state | recalling_firm | method_c | initial_firm | distributio | product_c | recall_rea | recall_start | recall_end | recall_time_days |
|---------|-------------|-------|------------------------------------|------------|--------------|-------------|-----------|-------------|--------------|------------|------------------|
| Ongoing | Marlborou | MA | Boston Scientific Corporation | Voluntary: | Letter | Global | 6635 | Faulty Des | 2/2/2023 | 4/26/2023 | 83 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 10 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 6 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 4 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 6 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 4 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 13 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 6 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 6 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 4 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 4 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 14 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 4 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 27 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 10 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 3 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 10 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 1 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 2 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 30 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 8 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Stafford Sp | CT | Hobbs Medical, Inc. | Voluntary: | Letter | Global | 8 | Incorrect L | 7/29/2022 | 10/19/2022 | 82 |
| Ongoing | Indianapol | IN | Roche Diagnostics Operations, Inc. | Voluntary: | Letter | National | 684 | Faulty Des | 2/7/2020 | 3/11/2020 | 33 |
| Ongoing | Marlborou | MA | Boston Scientific Corporation | Voluntary: | Letter | Global | 542 | Incorrect L | 10/21/2019 | 12/4/2019 | 44 |

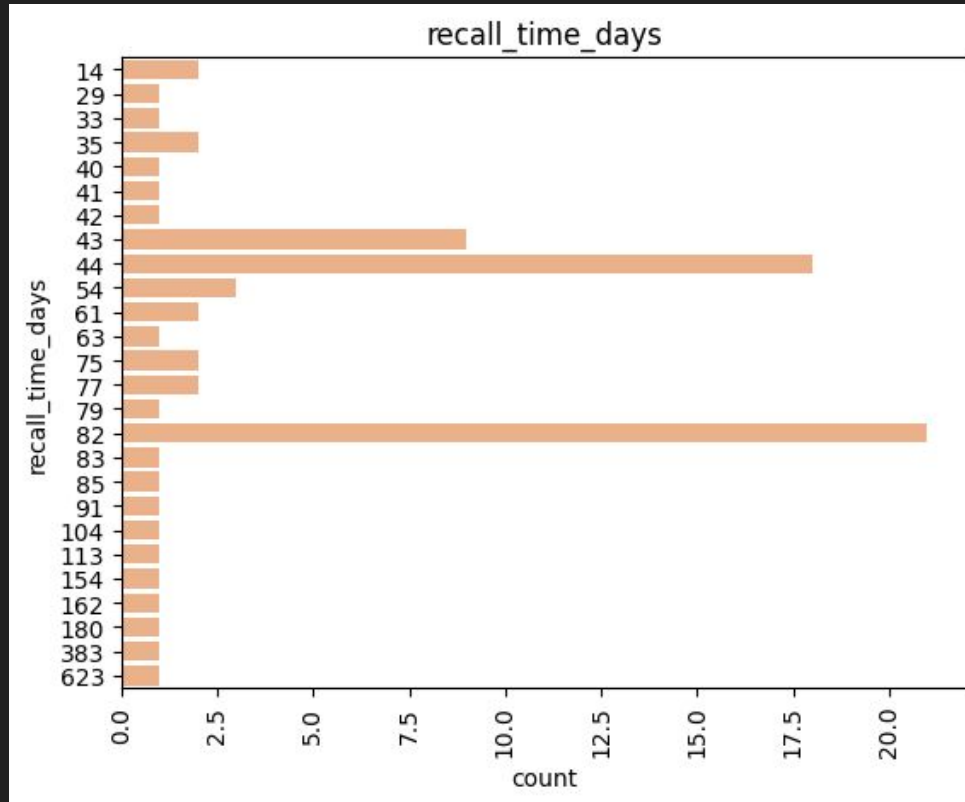
Firms device recall



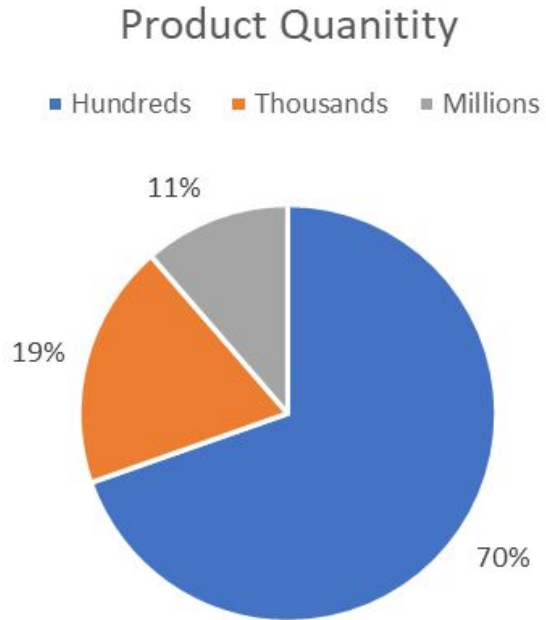
Reasons for recalls



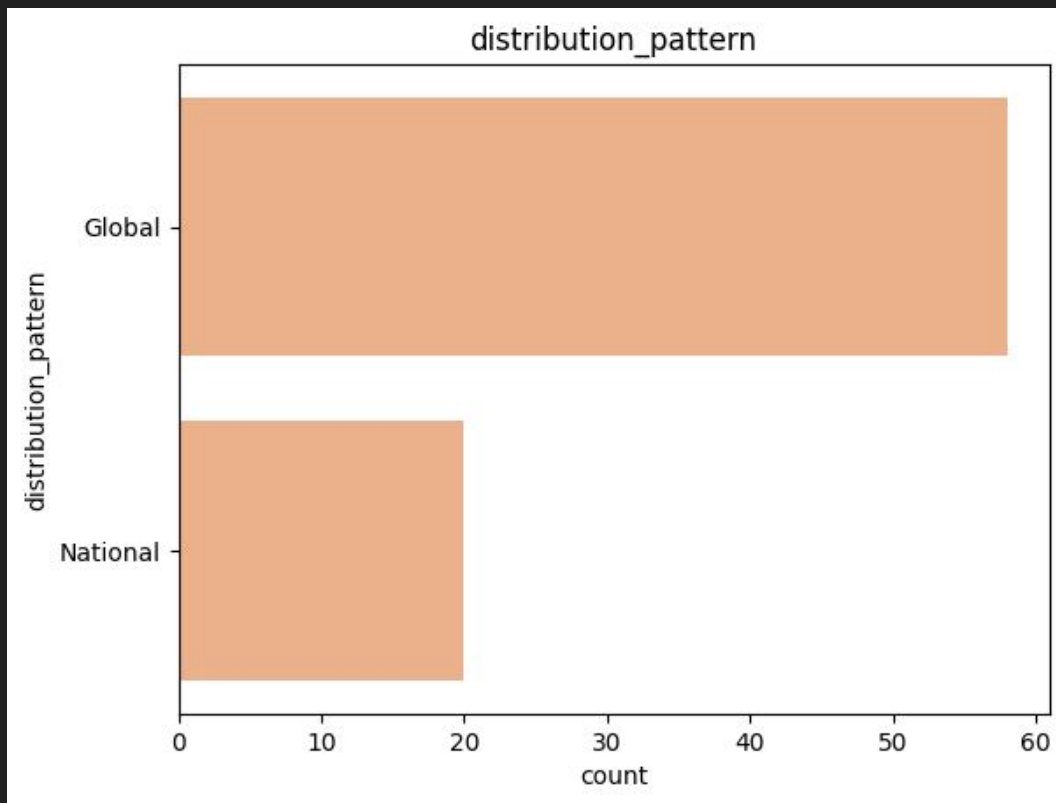
Recall Timeline Distribution



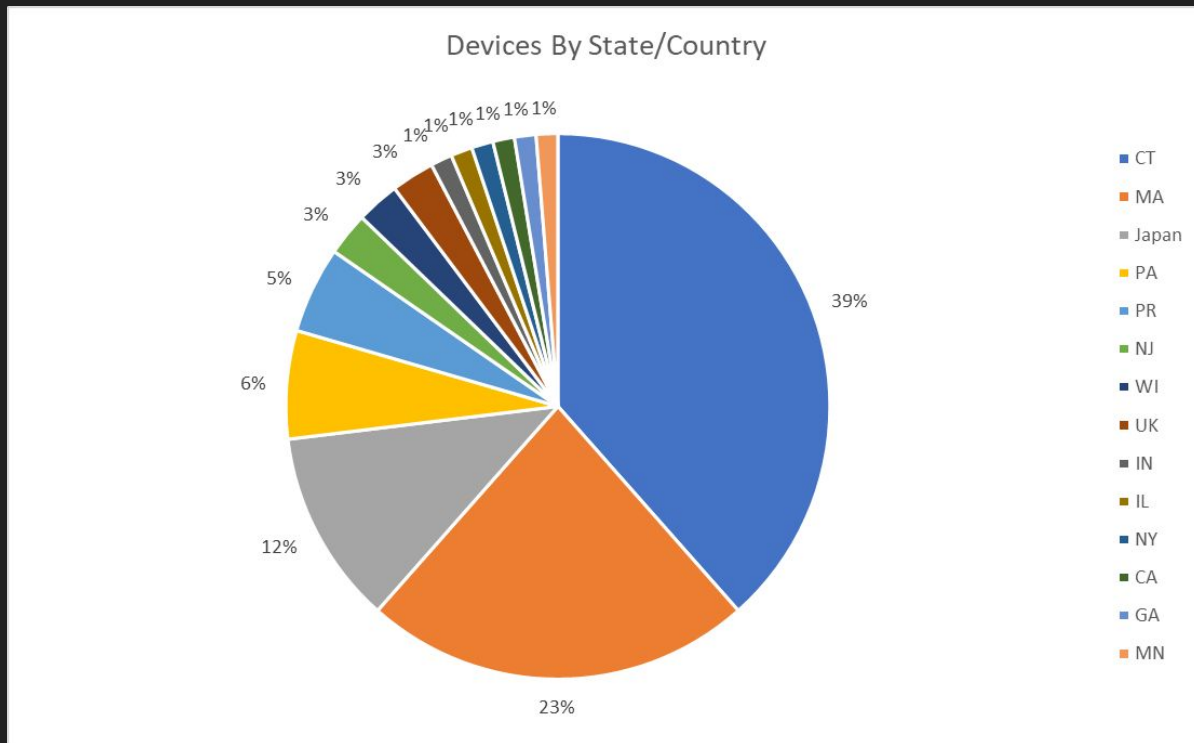
Spread Of Recalls



Distribution



Distribution



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Zuckerman, D. M., Brown, P., & Nissen, S. E. (2011). Medical device recalls and the FDA approval process. *Archives of internal medicine*, 171(11), 1006-1011.

Zhou, X., Kouzel, M., Ren, H., & Alemzadeh, H. (2022, November). Design and validation of an open-source closed-loop testbed for artificial pancreas systems. In 2022 IEEE/ACM Conference on Connected Health: Applications, *Systems and Engineering Technologies* (CHASE) (pp. 1-12). IEEE.

Questions?

Thanks for Listening