

Workshop – FDA 510(k) Submission

Singapore Biodesign – A*STAR Research Entities

Tim LIN

EMERGO by UL | Senior RA/QA Consultant

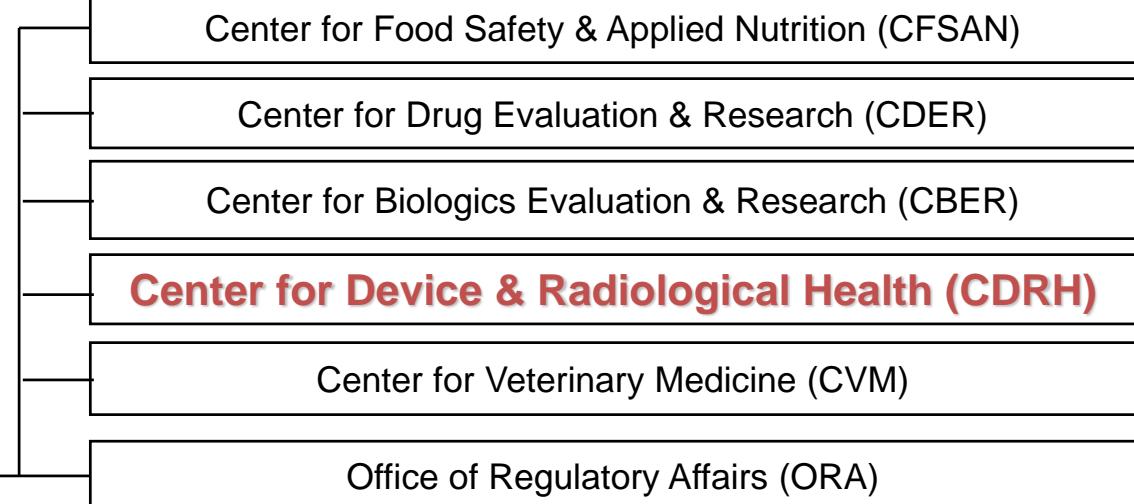
Tim.Lin@ul.com

FDA Organization

**U.S. FOOD & DRUG
ADMINISTRATION**



FDA Controls: Food, Drug, Biologics, medical device, Cosmetics, Laser product, Veterinary medicine



Medical Device Amendments

- Established Section 510(k)
- Classification of Devices
 - Class I General Controls
 - Class II General & Special Controls
 - Class III PMA (Pre-Market Approval)
- 1700+ distinct types of devices
- 16 Device Panels (medical specialty)

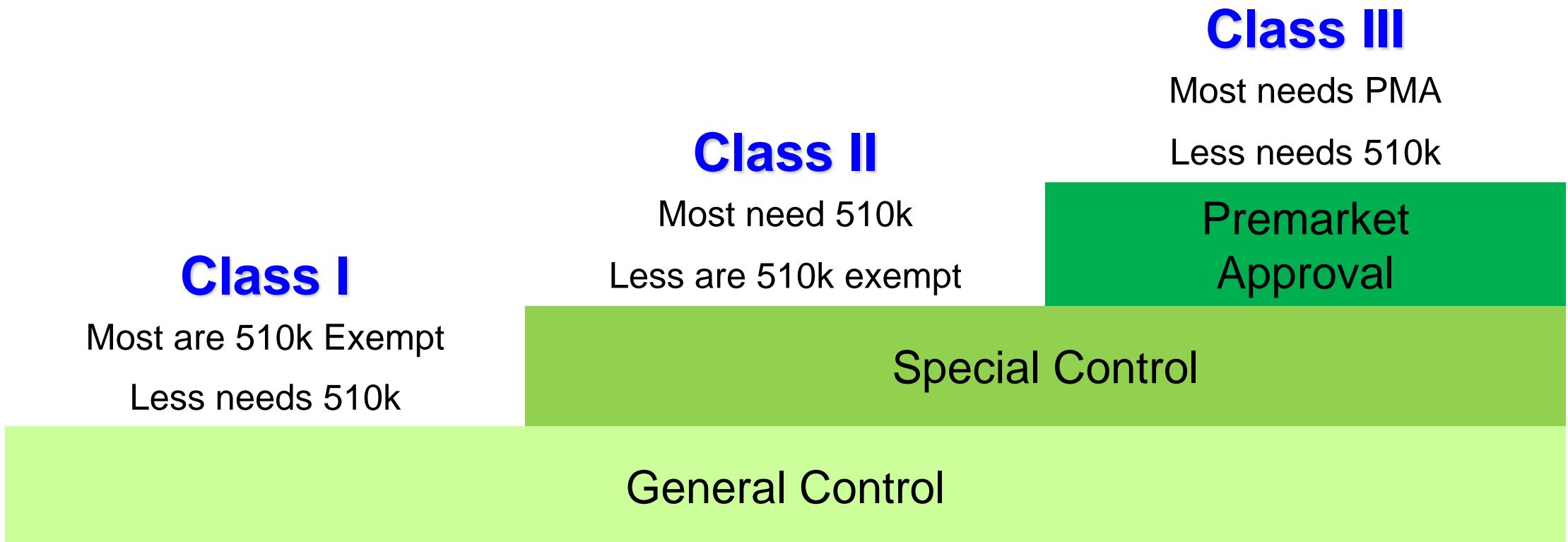
General Controls

- Registration of manufacturing location
- Listing of marketed medical devices
- Premarket notification
- Protection against Adulteration, Misbranding & Banned devices
- Good Manufacturing Practices
 - Record Keeping
 - Complaint Handling

Special Controls

- Specific to Class II devices
- Usually for well-established device types
- Examples:
 - Performance Standards
 - Postmarket Surveillance
 - Patient Registries
 - Special Labeling Requirements (e.g., 882.5970 Cranial Orthosis)
 - Pre-market data requirements
 - Guidance Documents (e.g. Use of ISO 10993-1 Ultrasound, Blood Glucose Monitoring System)

Classification



There are a small percentage of class I devices that require a 510(k) and small percentage of class II that are exempt.

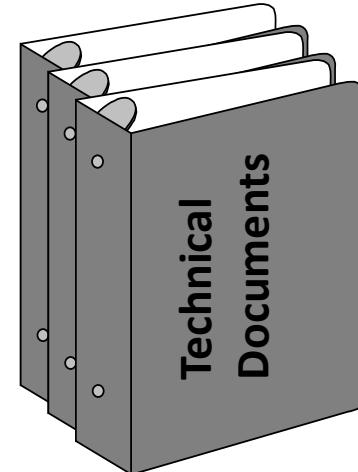
What is a 510(k)-Exempt ?

- Substantial review is NOT required.
- Still need Register and Listing
- Clearly defined by FDA

What is a 510(k)?

Pre-Market Notification

- An application submitted to the FDA by a person intending to introduce a medical device into interstate distribution.
- It demonstrates that the device to be marketed is **substantially equivalent** to a legally marketed device



Premarket Approval – PMA

- Highest Tier of Scientific Review
- No need to “Compare” with legally marketed device (predicate)
- More stringent review process, takes years.
- With clinical study data
- On-site inspection before review
- Involvement of advisory committee
- Publish SSED (Summary of Safety and Effectiveness Data) for this device

PMA Review Process

- ODE filing review
- OSB statistical review for filing
- OC review of manufacturing information for compliance with the Quality System regulation (21 CFR 820).
- PMA filing decision
- Day-100 Meeting
- Quality System Inspection(s) by the FDA field personnel. An FDA manufacturing inspection is conducted for all original PMAs and may be conducted for PMA supplements requesting approval of alternate or additional manufacturing and sterilization facilities.
- Bioresearch Monitoring (BIMO) Audit (audit of clinical study data)
- Substantive review coordination and completion in areas such as:
 - Preparation of FDA Summary of Safety and Effectiveness Data (SSED)
 - Nonclinical Studies
[Microbiological, Toxicological, Immunological, Biocompatibility, Shelf Life, Analytical (for IVDs), Animal, Engineering (Stress, Wear, Fatigue, etc.)]
 - Clinical Studies
 - Panel Meeting Decision and Mailing (if panel meeting is appropriate)
 - Panel Date (if appropriate)
 - Transcripts Received, Reviewed and Placed in Administrative Record
 - QS/GMP Clearance
 - Final Response from OC for GMP/BIMO
 - Final ODE Decision Memo
 - Approval Package
 - Approval Order, SSED, Final Draft Labeling

De Novo REQUEST

- Marketing process for **novel** devices
- Device has **no existing classification regulation** or **no identifiable predicate device**
- May create new classification regulation
- Alternative to PMA or 510(k) with NSE decision

De Novo REQUEST

De Novo Request

- A pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, *but for which there is no legally marketed predicate device*.
- De Novo classification is a risk-based classification process.

Options for applying De Novo Request

Option 1:

After receiving a high-level not substantially equivalent (NSE) determination (i.e., new intended use and/or different technological characteristics that raise different questions of safety and effectiveness) in response to a 510(k) submission.

Option 2:

Upon the sponsor's determination that there is no legally marketed device upon which to base a determination of substantial equivalence (therefore without first submitting a 510(k) and receiving a high-level NSE determination).

Submission Content

- Administrative Information
- Regulatory History
- Device Information and Summary
- Indications for Use
- Change Summary (if appropriate)
- Classification Summary
- Classification Recommendation (Proposed Special Controls for Class II)
- Supporting Protocols and/or Data
- Summary of Benefits
- Summary of Identified Risks to Health
- Risk and Mitigation Information
- Benefit-Risk Considerations
- Device Labeling

User Fee

FY 2019 User Fees (in U.S. Dollars)

Application Type	Standard Fee	Small Business Fee†
510(k)‡	\$10,953	\$2,738
513(g)	\$4,349	\$2,175
De Novo classification	\$96,644	\$24,161
PMA, PDP, PMR, BLA	\$322,147	\$80,537
panel-track supplement	\$241,610	\$60,403
180-day supplement	\$48,322	\$12,081
real-time supplement	\$22,550	\$5,638
BLA efficacy supplement	\$322,147	\$80,537
Annual Report	\$11,275	\$2,819
30-day notice	\$5,154	\$2,577

† For small businesses with an approved SBD.

‡ Note: all types of 510(k)s (Traditional, Abbreviated, and Special) are subject to the user fee. However, there is no user fee for 510(k)s submitted to the FDA on behalf of an FDA-accredited third-party reviewer.

A small business is defined as a business, including its affiliates, whose gross receipts and sales are less than \$100 million for the most recent tax year.

Small businesses with an approved SBD with gross receipts or sales of \$30 million or less are eligible to have the fee waived on their **first** PMA, PDP, PMR, or BLA.

Annual Establishment Registration Fee: \$4,884

There are no waivers or reductions for small establishments, businesses, or groups – all establishments must pay the establishment registration fee.

Quality System Regulation: 21 CFR 820

CFR – Code of Federal Regulations

- Chapter 21 – relates to Food & Drugs

Codifies all FDA regulations (e.g.)

- 21 CFR 801 Labelling
- 21 CFR 807 Registration, Listing and PMN
- **21 CFR 820 Quality System Regulations**
- 21 CFR 862-892 Device Description and Classification
- 21 CFR 1000-1050 Radiological Health

Registration and Listing

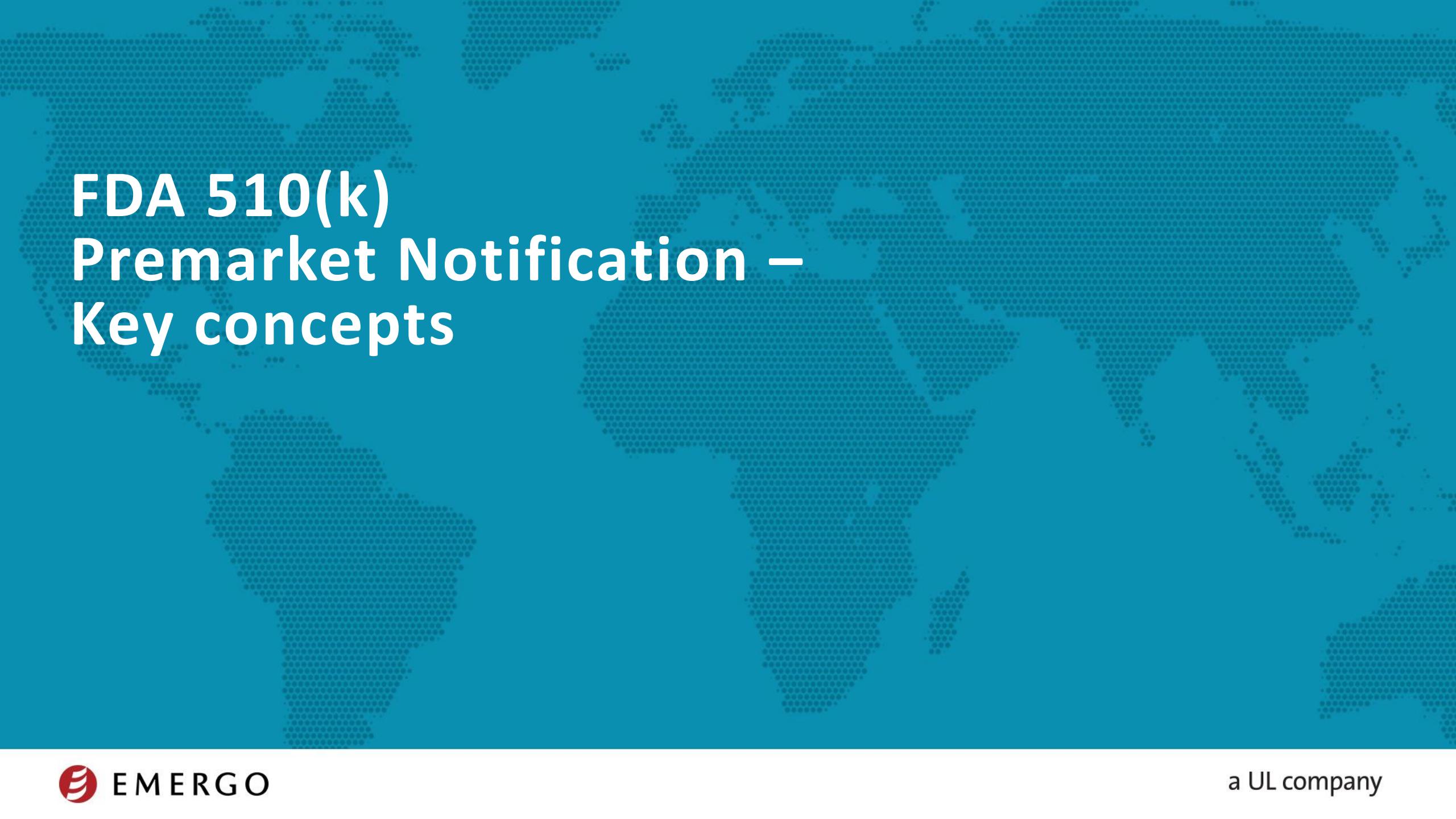
Registration:

- Establishments who **manufacture, propagate, prepare, compound, assemble or process** a device must register within 30 days of after beginning any of the above
- Includes activities such **as repackaging, re-labelling, distribution, importing** or specifications development

Annual Establishment Registration Fee: \$4,884 (FY 2019)

Listing :

- Classifications of devices listed in commercial distribution
- No need to re-list annually



FDA 510(k) Premarket Notification – Key concepts

What is a 510(k)?

A 510(k) NOT

- FDA Approval of a device
 - Rather the FDA grant clearance to a SE 510(k) submission
- A form
- Registration, Listing or QSR/QSIT Inspection

When is a 510(K) Required?

- Introduction of a new device into interstate commerce
- A different intended use for an existing device in interstate distribution
- Change or modification to an existing device that could effect its safety or effectiveness

When is a 510 (k) NOT Required?

- Sale of unfinished devices to another firm for further processing
- If device is for clinical trial (IDE) or subject to PMA
- Distribute other manufacturers devices
- Re-labellers unless labelling is significantly effected
- If device was in commercial distribution before May 28, 1976
- Importer of foreign made medical device which is 510k cleared.
- Exempted by regulation in 21 CFR

Who should submit a 510(k)?

- All manufacturers of devices subject to 510(k)?
 - ✓ Domestic manufacturers introducing a device to the U.S. market;
 - ✓ Specification developers introducing a device to the U.S. market;
 - ✓ Re-packers or re-labelers who make labeling changes or whose operations significantly affect the device
 - ✓ Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market.

Traditional 510(k)

The traditional 510(k) process is a regulatory pathway for medical devices that have been modified from an already approved device. This process involves submitting a premarket notification (510(k)) to the U.S. Food and Drug Administration (FDA) to demonstrate that the new device is substantially equivalent to a legally marketed device. The submission must include a detailed description of the device, its intended use, and the results of clinical trials or other testing to support its safety and effectiveness.

The traditional 510(k) process is generally faster and less expensive than the PMA process, but it requires a demonstration of substantial equivalence, which can be challenging if the device is significantly different from the predicate device. The FDA has the authority to require additional information or testing if they have concerns about the device's safety or effectiveness.

It is important to note that the traditional 510(k) process is not available for all medical devices. Devices that pose a significant risk to health or safety, or those that are intended to treat life-threatening conditions, may require a more rigorous review process, such as the Premarket Approval (PMA) process.

Traditional 510(k)

- Used for any original 510(k)
- For a modification to a previously cleared device under 510(k).
- Used under any circumstances (New device eligible for 510k, revision of the device, etc.)

Abbreviated 510(k)

Abbreviated 510(k)

- Guidance documents exists
- A special control is established
- FDA has recognized consensus standards



Special 510(k)

Special 510(k)

Modifications to own device only

Utilizes certain aspects of QSR

- Pre-production Design Controls

FDA able to forgo a detailed review of design data

Valid only if no change to:

- Indications for Use
- Labelling change affecting Intended Use
- Fundamental Scientific Technology
- Critical Materials not previously marketed in similar class of device

Predicate Device

Predicate Device

You may compare your device to:

- A legally marketed device in interstate commerce before May 28, 1976 (Pre-amendment device)
- A device found SE through the 510(k) process
- May be more than 1 device, but not to a device that would require a PMA if being marketed today

What is a Predicate Device?

- A **legally marketed device**, previously cleared through the 510(k) process mainly, that is used for comparison to a new device for the purpose of determining substantial equivalence (21 CFR 807.92(a)(3)).
- **Choose your predicate device carefully !**

Substantial Equivalence

Premarket Notification 510(k)

- **Market application** for low and moderate risk devices
- Compare “**Substantial Equivalence**” between new device and a legally marketed device. Demonstrate
- A new device, as compared to a **predicate device**, has...
 - the **same intended use**
 - the **same technological characteristics**
 - Or **differences** in technological characteristics do not raise different questions regarding safety and effectiveness.
- 510(k)s are “**cleared**” NOT “**approved**”

Substantial Equivalence

- Does not mean a new device has to be identical
- SE is established with respect to intended use, design, energy used or delivered
- If a new device has a new Intended Use, it is NSE (Non-SE)
- If it has same Intended Use but different Technological Features

FDA Essential Database Introduction and Practice

Tim LIN

EMERGO by UL | Senior RA/QA Consultant
Tim.Lin@ul.com

FDA Homepage

<https://www.fda.gov/>



FEATURED

Plan, Prepare And Protect Your Pet Before, During And After An Emergency

When it comes to planning for emergencies, pet owners should consider their pets too.

FEATURED INFORMATION

**Test Plan for the Digital Health Software Precertification Program**

Companies who plan in the next year to submit a premarket application for software as a medical device (SaMD) may participate.

**Devices for Diabetes Management: FDA Safety Communication**

The FDA warns against the use of devices for diabetes management not authorized for sale in the U.S.

**Artificial Intelligence and Machine Learning in Software**

Read the new discussion paper on Artificial Intelligence and Machine Learning-Based Software as a Medical Device.



NAVIGATE THE MEDICAL DEVICE SECTION

Device Advice

Information, education, and support for industry

Medical Device Safety

Safety Communications, Recalls, Letters to Health Care Providers, Reporting Adverse Events (MDR and MedSun)

Products and Medical Procedures

Approvals and clearances, information on medical devices by type

Digital Health

Cybersecurity, mobile medical applications, wireless medical devices, Software as Medical Device (SaMD)

CDRH research programs, epidemiology, medical device development tools (MDDT)

International Medical Device Regulators Forum, Medical Device Single Audit Program (MDSAP)

CDRHNew daily updates, webinars, meetings, workshops, conferences

Information for consumers and health care providers, letters to industry

SEARCH MEDICAL DEVICE DATABASES



510(k) Premarket Notification Database

Device Registration and Listing Database

Product Code Classification Database



MAUDE (Manufacturer and User Facility Device Experience) Database

Premarket Approvals (PMA) Database

All Medical Device Databases



HOW DO I

Classify a Medical Device

Register and List a Device

Label a Device

Submit Adverse Event and Problem Reports (MDR)

HOW DO I

[Classify a Medical Device](#)[Register and List a Device](#)[Label a Device](#)[Submit Adverse Event and Problem Reports \(MDR\)](#)[Study and Market a Device](#)[Find Device Approvals and Clearances](#)[Find Device Recalls](#)[Watch Webinars](#)

FIND GUIDANCE DOCUMENTS

[Final Guidances](#)[Draft Guidances](#)[Search for Guidances](#)

GET INFORMATION ON CDRH

[About the Center for Devices and Radiological Health](#)[CDRH Management Directory by Organization](#)[CDRH New Daily Updates](#)[Sign Up for Emails](#)

Practice:

Please search following specific topic

- Digital Health
- Artificial Intelligence
- Breakthrough Device Program

All Medical Device Databases

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>

按一下回上一頁，按住可查看記錄

Science and Research

CDRH research programs, epidemiology, medical device development tools (MDDT)

International Programs

International Medical Device Regulators Forum, Medical Device Single Audit Program (MDSAP)

News & Events

CDRH New daily updates, webinars, meetings, workshops, conferences

Resources for You

Information for consumers and health care providers, letters to industry

SEARCH MEDICAL DEVICE DATABASES

510(k) Premarket Notification Database

Device Registration and Listing Database

Product Code Classification Database

MAUDE (Manufacturer and User Facility Device Experience) Database

Premarket Approvals (PMA) Database

All Medical Device Databases

HOW DO I

Medical Device Databases

[!\[\]\(363fc38c109e5b10fbbc4ae1930fe25a_img.jpg\) Share](#) [!\[\]\(7562550e72e03335d55b23b9dd7c1169_img.jpg\) Tweet](#) [!\[\]\(11d4aeef32c02d10e1e99bc8297e3125_img.jpg\) LinkedIn](#) [!\[\]\(9a76ed516917b09cefb77b499e196a5a_img.jpg\) Email](#) [!\[\]\(d56ef606e75833a0937af365dcbfcb92_img.jpg\) Print](#)

Medical Device Databases	Title	Description	Updated	More Information	Content current as of:
	AccessGUID (Global Unique Device Identification Database)	This database contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).	Daily	More about GUDID	03/27/2018
	Advisory Committee/Panel Meetings - CDRH	This database contains historical information about CDRH Advisory Committees and Panel meetings through 2008, including summaries and transcripts.	No longer being updated	FDA Advisory Committees and Meeting Materials	
	CDRH Export Certificate Validation (CECV)	This searchable database contains valid (not expired) export certificates submitted electronically via CECATS (CDRH Export Certification Application and Tracking System) and issued by the Center for Devices and Radiological Health. The results displayed include the facility name, certificate type, expiration date, certificate number, and the number of pages per certificate.	Weekly		
	CFR Title 21 - Food and Drugs	This database contains the most recent revision from the Government Printing Office (GPO) of the Code of Federal Regulations (CFR) Title 21 - Food and Drugs.	Annually	More About 21CFR	
	Clinical	This database contains the commercially marketed in vitro test systems categorized by the FDA since	Weekly	Clinical	

Practice:

Please identify following database

- Product Classification
- PMA Database
- 510(K) Database
- Recognized Consensus Standards
- Total Product Life Cycle

Guidance database

<https://www.fda.gov/regulatoryinformation/guidances/default.htm>

HOW DO I

Classify a Medical Device

Register and List a Device

Label a Device

Submit Adverse Event and Problem Reports (MDR)

Study and Market a Device

Find Device Approvals and Clearances

Find Device Recalls

Watch Webinars

FIND GUIDANCE DOCUMENTS

Final Guidances

Draft Guidances

Search for Guidances

About the Center for Devices and Radiological Health

CDRH Management Directory by Organization

CDRH New Daily Updates

Sign Up for Emails

Search for FDA Guidance Documents

[Subscribe to Email Updates](#) [Share](#) [Tweet](#) [Linkedin](#) [Email](#) [Print](#)

[Search for FDA Guidance Documents](#)

[Search General and Cross-Cutting Topics Guidance Documents](#)

[Advisory Committee Guidance Documents](#)

[Clinical Trials Guidance Documents](#)

[Combination Products Guidance Documents](#)

[Import and Export Guidance Documents](#)

The table below lists all official FDA Guidance Documents and other regulatory guidance. You can search for documents using key words, and you can narrow or filter your results by product, date issued, FDA organizational unit, type of document, subject, draft or final status, and comment period.

This feature is provided to give a convenient way to search for all FDA guidance documents from a single location.

If you cannot find the document you're looking for here, you can browse separate collections of guidance documents by topic.

[Go to Guidance Document Search](#)

Content current as of:
05/09/2019

[Browse Guidance Documents By Topic](#)

Guidance Document Search

Search

Showing 1 to 10 of 2,848 entries

Filters

Product**FDA Organization****Topic****Issue Date****Draft or Final****Open for Comment****Document Type****Comment Closing Date on Draft***

[Clear Filters](#)

[Export Excel](#)

Show

10



entries

Practice:

Please identify following guidance

- Traditional 510(k) – related guidance
- Biocompatibility - related guidance
- 3D Printing – related guidance
- Home use – related guidance

Product classification and risk class



SEARCH

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Product Classification

● FDA Home ● Medical Devices ● Databases



This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

[Learn More...](#)

Search Database



Help



Download Files

Device

Product Code

Review Panel

Regulation Number

Submission Type

Third Party Eligible

Implanted Device

Device Class

[Go to Quick Search](#)

[Clear Form](#)

[Search](#)

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

Practice:

Please identify following device w.r.t:
Identification, Risk Class, Submission route

- Catheter (DQY)
- Injector (NSC)
- X-ray (IYO)

510(k) Database

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

510(k) Premarket Notification

FDA Home Medical Devices Databases



A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.

[Learn more...](#)

Search Database



Help



Download Files

510K Number

Type

Product Code

Center

Combination Products

Applicant Name

Cleared/Approved In Vitro Products

Device Name

Redacted FOIA 510(k)

Panel

Third Party Reviewed

Decision

▼

Decision Date

 to

Clinical Trials

Sort by

▼

[Quick Search](#)

[Clear Form](#)

[Search](#)

Other Databases

- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

Practice:

Please Search following product according to

- product name including “Ultrasound”
- product brand as “Medtronic”
- product code as “CAF”

Recognized Standards Database

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

Recognized Consensus Standards

FDA Home Medical Devices Databases



The CDRH Standards Program:

- Created as a result of the Food and Drug Administration Modernization Act (FDAMA) of 1997. The Standards Management Staff (SMS) is responsible for facilitating the recognition of national and international medical device consensus standards.
- Modifications to the list of recognized consensus standards: Publications in the Federal Register to the list of recognized consensus standards can be accessed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>.
- Please note that changes to the recognized consensus standards database are updated the following Monday.

[Learn More...](#)

Search Database



Standards Organization

All Standards Organizations

Standard Designation Number

Note: numbers only, e.g., 14971, 60601-1

Standards Title or Keywords

Note: do not include standard designation number

(30 chars. max)

Specialty Task Group Area

All Categories

Product Classification Product Code

e.g., for vertical standard searches

Regulation Number (e.g., 888.1111)

Type of Standard

(use ctrl button with mouse click to select up to 3 types, e.g., Horizontal, National, Materials Specification)

All Standard Types

Vertical

Test Methods

National

FR List Publication Date

From



To



Sort By

Product Area, Item #

[Quick Search](#)

[Clear Form](#)

[Search](#)

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Total Product Life Cycle
- X-Ray Assembler

Practice:

Please search information w.r.t

- IEC 60601-1-2:2014 relevant information
- IEC 18562 relevant information
- Which version of “IEC 62366” is recognized ?
- What is recognized standards for product code: IZL ?

Total Product Life Cycle, TPLC

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm>

TPLC - Total Product Life Cycle

[FDA Home](#) [Medical Devices](#) [Databases](#)



[510\(k\)](#) | [DeNovo](#) | [Registration & Listing](#) | [Adverse Events](#) | [Recalls](#) | [PMA](#) | [HDE](#) | [Classification](#) | [Standards](#)
[CFR Title 21](#) | [Radiation-Emitting Products](#) | [X-Ray Assembler](#) | [Medsun Reports](#) | [CLIA](#) | [TPLC](#)

This database includes:

- premarket and postmarket data about medical devices. It includes information pulled from CDRH databases including Premarket Approvals (PMA), Premarket Notifications (510[k]), Adverse Events, and Recalls.

[Learn More...](#)

Search Database



Device

Product Code

Regulation Number

Since

 ▾

[Clear Form](#)

[Search](#)

Other Databases

- [510\(k\)s](#)
- [De Novo](#)
- [Medical Device Reports \(MAUDE\)](#)
- [CDRH Export Certificate Validation \(CECV\)](#)
- [CDRH FOIA Electronic Reading Room](#)
- [CFR Title 21](#)
- [CLIA](#)
- [Device Classification](#)
- [FDA Guidance Documents](#)
- [Humanitarian Device Exemption](#)
- [Medsun Reports](#)
- [Premarket Approvals \(PMAs\)](#)
- [Post-Approval Studies](#)

Practice:

Please search what issues has ever happened of
following product code

- Catheter
- Nebulizer (CAF)
- Product Code: FRN

FDA Forms

<https://www.fda.gov/about-fda/reports-manuals-forms/forms>

FDA Forms

[Share](#) [Tweet](#) [LinkedIn](#) [Email](#) [Print](#)

FDA Forms

Information and Instructions

Requesting Forms from the Warehouse

If you have problems opening a PDF form in your browser, try downloading it instead:

1. Right-click the form link.
2. Click the **Save** option. (On most browsers, this is the **Save Link As** option.)
You may also need to [upgrade your version of Adobe Reader](http://get.adobe.com/reader/) ↗ <http://get.adobe.com/reader/> ↗

Content current as of:
02/02/2018

Search

Showing 1 to 10 of 338 entries

Filters

Center

Practice:

Please search following table

- Form 3514
- Form 3881

Case Study – How to prepare a 510(k) Submission

SIX STEPS - PREPARING A 510(k)

Step 1. Establish device name and type

Step 2. Determine the classification

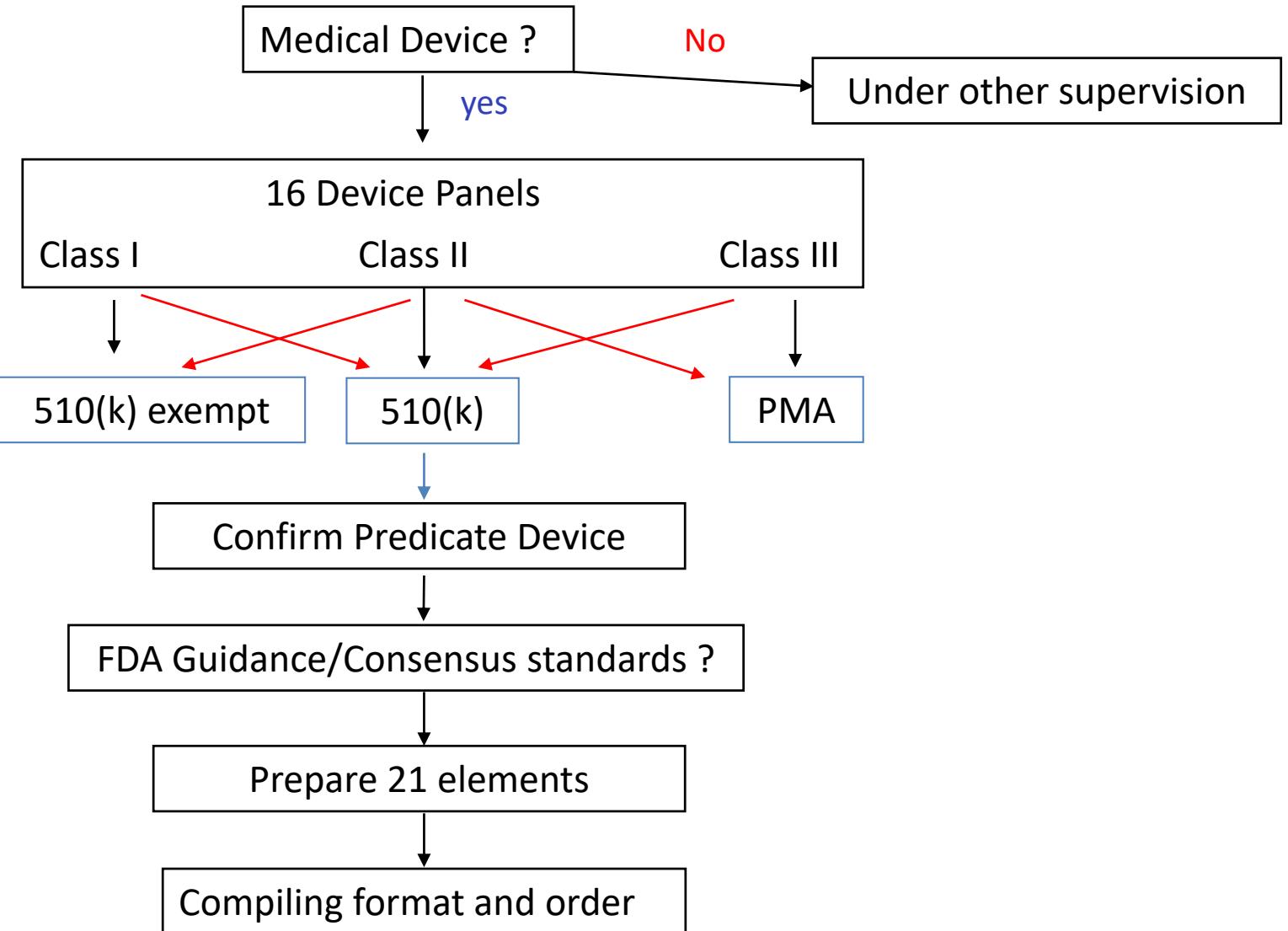
Step 3. Find a predicate device

Step 4. Locate guidance documents

Step 5. Determine content

Step 6. Assemble the submittal

1. ESTABLISH TO DEVICE NAME AND TYPE
2. DETERMINE THE CLASSIFICATION
3. FIND A PREDICATE DEVICE
4. LOCATE GUIDANCE DOCUMENTS
5. DETERMINE CONTENT
6. ASSEMBLE THE SUBMITTAL



Step 1. Establish device name and type.

Is it a medical device ? Such as: dental chair, sterilizer, or hospital bed, Medical Monitor

- See (<https://www.fda.gov/medical-devices/classify-your-medical-device/product-medical-device>)
- Unknown ? Ask FDA
 - 513(g) Requests for Information

Device Name and Type

- Recommend to see
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdc/classification.cfm>)

Step 2. Determine the classification

Determine Classification

- Is your device class I, or class II, or class III??
 - See the FDA website
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdc/classification.cfm>

How to classify your device?

To find the classification of your device, as well as whether any exemptions may exist, you need to **find the regulation number** that is the classification regulation for your device.

There are three methods for accomplishing this:

- 1) Go directly to the [classification database](#) and search for a part of the device name,
- 2) If you know the [device panel](#) (medical specialty) to which your device belongs, go directly to the listing for that panel and identify your device and the corresponding regulation.
- 3) According to your competitor's (similar product) information

1. Confirm product classification

Key word : Ultraso

The screenshot shows the 'Product Classification' page on the FDA website. The URL is https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm. The page title is 'Product Classification'. Below the title, there are three navigation links: 'FDA Home', 'Medical Devices', and 'Databases'. On the right side, there are icons for printing, adding to favorites, and email. A sidebar on the right lists 'Other Databases' including 510(k)s, De Novo, Medical Device Reports (MAUDE), CDRH Export Certificate Validation (CECV), CDRH FOIA Electronic Reading Room, CFR Title 21, CLIA, FDA Guidance Documents, Humanitarian Device Exemption, Medsun Reports, Premarket Approvals (PMAs), Post-Approval Studies, Postmarket Surveillance Studies, Radiation-Emitting Products, Radiation-Emitting Electronic Products Corrective Actions, Recalls, Registration & Listing, Standards, Total Product Life Cycle, and X-Ray Assembler.

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

[Learn More...](#)

Search Database

Device: Product Code:
Review Panel: Regulation Number:
SubmissionType: Third Party Eligible:
Implanted Device: Life-Sustain/Support Device:

[Go to Quick Search](#) [Clear Form](#) [Search](#)

IYO	System, Imaging, Pulsed Echo, Ultrasonic	Ultrasonic Pulsed Echo Imaging System	892.1500	2	
IYN	System, Imaging, Pulsed Doppler, Ultrasonic	Ultrasonic Pulsed Doppler Imaging System...	892.1550	2	
ITX	Transducer, Ultrasonic, Diagnostic	Diagnostic Ultrasonic Transducer	892.1570	2	
IMI	Ultrasonic Diathermy For Use In Applying Therapeutic Heat	Ultrasonic Diathermy	890.5300	2	
IMG	Stimulator, Ultrasound And Muscle, For Use In Application	Ultrasound And Muscle Stimulator	890.5860	2	
HHX	Holograph, Fetal, Acoustical	Obstetric-Gynecologic Ultrasonic Imager	884.2225	2	
HHJ	Locator, Intracorporeal Device, Ultrasonic, Obstetric	Obstetric-Gynecologic Ultrasonic Imager	884.2225	2	
HGL	Transducer, Ultrasonic, Obstetric	Obstetric Ultrasonic Transducer And Accessory	884.2960	2	
HEQ	Monitor, Pressure, Arterial, Fetal, Ultrasonic	Fetal Ultrasonic Monitor And Accessories...	884.2660	2	

Device Panel

[862 Clinical Chemistry and Clinical Toxicology](#)

[864 Hematology and Pathology](#)

[866 Immunology and Microbiology](#)

[868 Anesthesiology](#)

[870 Cardiovascular](#)

[872 Dental](#)

[874 Ear, Nose, and Throat](#)

[876 Gastroenterology and Urology](#)

[878 General and Plastic Surgery](#)

[880 General Hospital and Personal Use](#)

[882 Neurology](#)

[884 Obstetrical and Gynecological](#)

[886 Ophthalmic](#)

[888 Orthopedic](#)

[890 Physical Medicine](#)

[892 Radiology](#)

Device Panel: See <https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels>

Relevant Regulation Number

TITLE 21-FOOD AND DRUGS
CHAPTER I-FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 892 RADIOLOGY DEVICES

Subpart A--General Provisions

- [§ 892.1 - Scope.](#)
- [§ 892.3 - Effective dates of requirement for premarket approval.](#)
- [§ 892.9 - Limitations of exemptions from section 510\(k\) of the Federal Food, Drug, and Cosmetic Act \(the act\).](#)

Subpart B--Diagnostic Devices

- [§ 892.1000 - Magnetic resonance diagnostic device.](#)
- [§ 892.1100 - Scintillation \(gamma\) camera.](#)
- [§ 892.1110 - Positron camera.](#)
- [§ 892.1130 - Nuclear whole body counter.](#)
- [§ 892.1170 - Bone densitometer.](#)
- [§ 892.1180 - Bone sonometer.](#)
- [§ 892.1200 - Emission computed tomography system.](#)
- [§ 892.1220 - Fluorescent scanner.](#)
- [§ 892.1300 - Nuclear rectilinear scanner.](#)
- [§ 892.1310 - Nuclear tomography system.](#)
- [§ 892.1320 - Nuclear uptake probe.](#)
- [§ 892.1330 - Nuclear whole body scanner.](#)
- [§ 892.1350 - Nuclear scanning bed.](#)
- [§ 892.1360 - Radionuclide dose calibrator.](#)
- [§ 892.1370 - Nuclear anthropomorphic phantom.](#)
- [§ 892.1380 - Nuclear flood source phantom.](#)
- [§ 892.1390 - Radionuclide rebreathing system.](#)
- [§ 892.1400 - Nuclear sealed calibration source.](#)
- [§ 892.1410 - Nuclear electrocardiograph synchronizer.](#)
- [§ 892.1420 - Radionuclide test pattern phantom.](#)
- [§ 892.1540 - Nonfetal ultrasonic monitor.](#)
- [§ 892.1550 - Ultrasonic pulsed doppler imaging system.](#)
- [§ 892.1560 - Ultrasonic pulsed echo imaging system.](#)
- [§ 892.1570 - Diagnostic ultrasonic transducer.](#)
- [§ 892.1600 - Angiographic x-ray system.](#)
- [§ 892.1610 - Diagnostic x-ray beam-limiting device.](#)
- [§ 892.1620 - Cine or spot fluorographic x-ray camera.](#)

Relevant Regulation Number

New Search Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2018]
[CITE: 21CFR892.1550]

 See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892 -- RADIOLOGY DEVICES
Subpart B--Diagnostic Devices

Sec. 892.1550 Ultrasonic pulsed doppler imaging system.

(a) *Identification.* An ultrasonic pulsed doppler imaging system is a device that combines the features of continuous wave doppler-effect technology with pulsed-echo effect technology and is intended to determine stationary body tissue characteristics, such as depth or location of tissue interfaces or dynamic tissue characteristics such as velocity of blood or tissue motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

Device	System, Imaging, Pulsed Doppler, Ultrasonic
Regulation Description	Ultrasonic pulsed doppler imaging system.
Regulation Medical Specialty	Radiology
Review Panel	Radiology
Product Code	IYN
Premarket Review	Office of In Vitro Diagnostics and Radiological Health.(OIR)
Submission Type	510(k)
Regulation Number	892.1550
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Recognized Consensus Standards	
● 12-105 NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3	
● 12-228 IEC 61391-2 Edition 1.0 2010-01 Ultrasonics - Pulse-echo scanners - Part 2: Measurement of maximum depth of penetration and local dynamic range	
● 12-277 IEC 62127-1 Edition 1.1 2013-02 Ultrasonics -- Hydrophones -- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	
● 12-279 IEC 62127-03 Edition 1.1 2013-05 Ultrasonics -- Hydrophones -- Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz	
● 12-291 IEC 62127-2 Edition 1.1 2013-02 Ultrasonics -- Hydrophones -- Part 2: Calibration for ultrasonic fields up to 40 MHz	
● 12-292 IEEE Std 3333.2.1-2015 IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling	
● 12-293 IEC 60601-2-37 Edition 2.1 2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	
● 12-312 IEC 61391-1 Edition 1.1 2017-07 CONSOLIDATED VERSION Ultrasonics - Pulse-echo scanners - Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response	
● 12-316 IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERSION Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical	

Other similar product

From 510k Database, you can type device name, or product code

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

510(k) Premarket Notification

FDA Home Medical Devices Databases

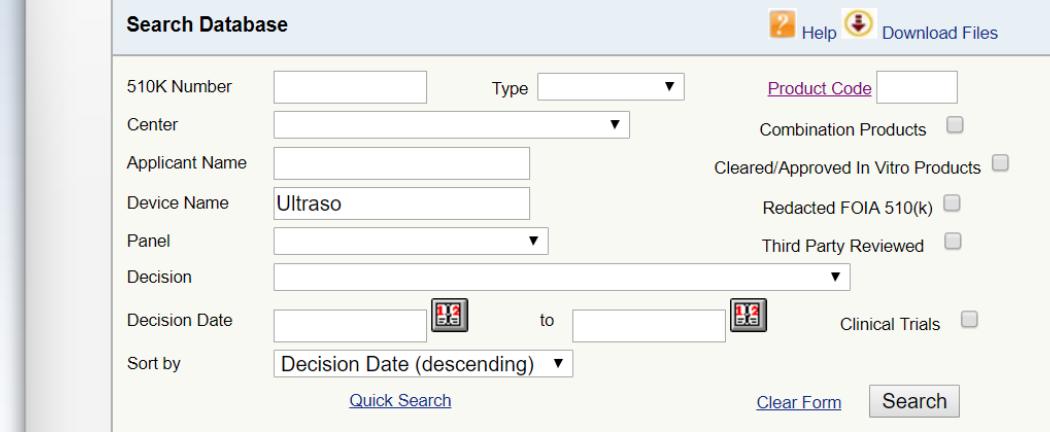
A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.
[Learn more...](#)

Search Database

Help Download Files

510K Number	Type	Product Code
Center		Combination Products
Applicant Name		Cleared/Approved In Vitro Products
Device Name	Ultraso	Redacted FOIA 510(k)
Panel		Third Party Reviewed
Decision		
Decision Date	to	Clinical Trials
Sort by	Decision Date (descending)	

Quick Search Clear Form Search



Other similar product

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

510(k) Premarket Notification

FDA Home Medical Devices Databases

1 to 10 of 500 Results *
Device Name: *Ultraso* Decision Date To:
07/14/2019

1 2 3 4 5 6 7 8 9 10 > Results per Page 10 ▾

New Search Export to Excel | Download Files | More About 510(k)

Device Name	Applicant	510(K) Number	Decision Date
Lightmed Ultrasound System	Lightmed USA, Inc	K183173	07/01/2019
Acist Kodama Intravascular Ultrasound Catheter, Acist Hdi System	ACIST Medical Systems, Inc.	K191175	06/27/2019
Transcranial Doppler Ultrasound System	Shenzhen Delica Medical Equipment Co., Ltd.	K190228	06/13/2019
Hs40 Diagnostic Ultrasound System	Samsung Medison Co., Ltd.	K191055	06/12/2019
Rs85 Diagnostic Ultrasound System	Samsung Medison Co., Ltd	K191115	06/12/2019
7410 Ultrasound System (MyLabsigma)	Esaote S.P.A.	K191072	06/10/2019
Tün® Ultrasonic Tips Product Family	Engineered Endodontics	K182145	06/07/2019
Nexus Ultrasonic Surgical Aspirator System	Misonix, Inc.	K190160	05/30/2019
Envision Ultrasound Pad And Cover	CIVCO Medical Solutions	K190802	05/24/2019
Pentax Medical Eb-1970uk Ultrasound Video Bronchoscope + Hitachi Noblus And Hi Vision Preirus	PENTAX Of America, Inc.	K183654	05/23/2019

* The maximum 500 devices meeting your search criteria returned. Please narrow your search.

Step 3. Find a predicate device

Find a predicate device

- What device or devices is being used for comparison?

- See the FDA website

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>

How to find a predicate device?

- The FDA 510(k) database contains all devices cleared under the 510(k) process.
- The classification of the device and product code is essential in searching for predicate devices.

Example: IYN (Ultrasonic pulsed doppler imaging system)

安全 | <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>

A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.
[Learn more...](#)

Search Database

510K Number Type Product Code
Center Combination Products
Applicant Name Cleared/Approved In Vitro Products
Device Name Redacted FOIA 510(k)
Panel Third Party Reviewed
Decision Clinical Trials
Decision Date to Decision Date (descending)
Sort by Quick Search Clear Form Search

Other Databases

- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

Example: IYN (Ultrasonic pulsed doppler imaging system)

安全 | <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>

510(k) Premarket Notification

FDA Home Medical Devices Databases

1 to 10 of 500 Results *
ProductCode: IYN Decision Date To:
11/04/2017

1 2 3 4 5 6 7 8 9 10 > Results per Page 10

Device Name	Applicant	510(K) Number	Decision Date
C5 Diagnostic Ultrasound System	Guangzhou Sonostar Technologies Co., Ltd	K171926	10/27/2017
M7/M7t/M7 Premium/M7 Expert/M7 Super Dia	Shenzhen Mindray Bio-Medical Electronics	K172970	10/25/2017
M6/M6t/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58	Shenzhen Mindray Bio-Medical Electronics	K171579	10/18/2017
Sonon Ultrasound Imaging System, Model:	Healcerion Co., Ltd	K170085	10/12/2017
Linkquest Diagnostic Ultrasound System M	Linkquest Inc.	K172059	10/05/2017
Philips Epiq 5 Diagnostic Ultrasound Sys	Philips Healthcare	K172607	10/04/2017
Voluson E6, Voluson E8, Voluson E10	Ge Healthcare	K172342	09/29/2017
U2 Diagnostic Ultrasound System	Edan Instruments Inc	K172380	09/29/2017
Zs3 Ultrasound System, Z.One Pro Ultraso	Shenzhen Mindray Bio-Medical Electronics	K171891	09/21/2017
S60 Series Digital Color Doppler Ultraso	Sonoscape Medical Corp.	K172082	09/21/2017

New Search Export to Excel | Download Files | More About 510(k)

Step 4. Locate Guidance Documents

- **General guidance** - Biocompatibility, Software, Electromagnetic Compatibility, Human Factor engineering, Home-use device, etc.
- **Product-specific guidance** - Technical information should be provided
- **Administrative information:** User fee, Refuse-To-Accept (RTA) policy, eCopy, etc.

These documents are available through the [Guidance Document](#) database.

Guidance Document Database

Search

Showing 1 to 7 of 7 entries (filtered from 2,848 total entries)

Filters

Product	FDA Organization
<input type="text"/>	<input type="text"/>

Topic	Issue Date
<input type="text"/>	<input type="text"/>

Draft or Final	Open for Comment
<input type="text"/>	<input type="text"/>

Document Type	Comment Closing Date on Draft*
<input type="text"/>	<input type="text"/>

Show entries

Available guidance for “Ultraso”

Summary	Document	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft
+ Marketing Clearance of Diagnostic Ultrasound Systems and Transducers : Guidance for Industry and Food and Drug Administration Staff	PDF (418.97 KB)	06/27/2019	Center for Devices and Radiological Health	Premarket,	Final	No	
+ Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (458.21 KB)	04/16/2018	Center for Devices and Radiological Health	Premarket,	Final	No	10/30/2017
+ Product Labeling for Certain Ultrasonic Surgical Aspirator Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (273 KB)	10/30/2017	Center for Devices and Radiological Health	Premarket, Labeling, Safety - Issues, Errors, and Problems	Final	No	01/09/2017
+ Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use - Guidance for Industry and FDA Staff		07/20/2011	Center for Devices and Radiological Health	Premarket,	Final	No	
+ Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner - Guidance for Industry and FDA Staff		11/07/2005	Center for Devices and Radiological Health	Premarket,	Final	No	
+ Guide for Preparing Product Reports for Ultrasonic Therapy Products (physical therapy only)	PDF (439.94 KB)	08/01/1996	Center for Devices and Radiological Health		Final	No	
+ CPG Sec. 397.100 Accuracy Requirements for Indication of Temporal-Maximum Ultrasonic Power, 21 CFR 1050.10(c)(1)(ii)		03/01/1995		Investigation & Enforcement,	Final	No	

Example: Diagnostic Ultrasound System and Transducers

Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

Guidance for Industry and Food and Drug Administration Staff

Document issued on: June 27, 2019

The draft of this document was issued on October 2, 2017.

This guidance document supersedes the guidance entitled “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” dated September 9, 2008.

For questions about this document, contact the Division of Radiological Health at 301-796-5790 or Shahram Vaezy (Office of Health Technology 7: Office of In Vitro Diagnostics and Radiological Health (OIR)) at 301-796-6242 or shahram.vaezy@fda.hhs.gov or Keith Wear (OSEL) at 301-796-2538 or keith.wear@fda.hhs.gov. For questions related to ultrasound systems and transducers intended for cardiovascular applications, contact the Office of Health Technology 2: Cardiovascular Devices at 301-796-7000. For questions related to ultrasound systems and transducers intended for obstetrics and gynecological applications, contact the Office of Health Technology 2: Reproductive, Gastro-Renal, Urological, General Hospital Device & Human Factors at 301-796-6650.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Use of Recognized Consensus Standard

- Significant role for substantial equivalence determinations.
- Helping characterize the device and has substituted for detailed descriptive information or performance data.
- Reduce reviewer's burden with a sound basis for SE determination.

Recognized Consensus Standards

Recognized Consensus Standards

• FDA Home • Medical Devices • Databases

The CDRH Standards Program:

- Created as a result of the Food and Drug Administration Modernization Act (FDAMA) of 1997. The Standards Management Staff (SMS) is responsible for facilitating the recognition of national and international medical device consensus standards.
- Modifications to the list of recognized consensus standards: Publications in the Federal Register to the list of recognized consensus standards can be accessed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>.
- Please note that changes to the recognized consensus standards database are updated the following Monday.

[Learn More...](#)

Search Database

Help

Standards Organization	All Standards Organizations
Standard Designation Number <small>Note: numbers only, e.g., 14971, 60601-1</small>	<input type="text"/> Recognition Number <input type="text"/>
Standards Title or Keywords <small>Note: do not include standard designation number</small>	<input type="text"/>
Specialty Task Group Area	All Categories
Product Code	<input type="text"/> Regulation Number <small>(e.g., 888.1111)</small> <input type="text"/>
Date of Recognition	<input type="text"/>  to <input type="text"/>  Sort <input type="text"/> Title of Stand (A-Z)
Quick Search Clear Form Search	

Recognized Consensus Standards

Recognized Consensus Standards

FDA Home Medical Devices Databases



1 to 9 of 9 Results

Product Classification Product Code: /YN

Results per Page 10 ▼

New Search						Export To Excel Help
Date Of Recognition	Specialty Task Group Area	Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard	
03/16/2012	Radiology	12-105	NEMA	UD 2-2004 (R2009)	Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment Revision 3	
08/14/2015	Radiology	12-292	IEEE	Std 3333.2.1-2015	IEEE Recommended Practice For Three-Dimensional (3D) Medical Modeling	
06/27/2016	Radiology	12-293	IEC	60601-2-37 Edition 2.1 2015	Medical Electrical Equipment - Part 2-37: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment	
06/07/2018	Radiology	12-316	IEC	62359 Edition 2.1 2017-09 CONSOLIDATED VERSION	Ultrasonics - Field Characterization - Test Methods For The Determination Of Thermal And Mechanical Indices Related To Medical Diagnostic Ultrasonic Fields	
06/07/2018	Radiology	12-312	IEC	61391-1 Edition 1.1 2017-07 CONSOLIDATED VERSION	Ultrasonics - Pulse-Echo Scanners - Part 1: Techniques For Calibrating Spatial Measurement Systems And Measurement Of System Point-Spread Function Response	
01/30/2014	Radiology	12-228	IEC	61391-2 Edition 1.0 2010-01	Ultrasonics - Pulse-Echo Scanners - Part 2: Measurement Of Maximum Depth Of Penetration And Local Dynamic Range	
07/09/2014	Radiology	12-279	IEC	62127-03 Edition 1.1 2013-05	Ultrasonics -- Hydrophones -- Part 3: Properties Of Hydrophones For Ultrasonic Fields Up To 40 MHz	
07/09/2014	Radiology	12-277	IEC	62127-1 Edition 1.1 2013-02	Ultrasonics -- Hydrophones -- Part 1: Measurement And Characterization Of Medical Ultrasonic Fields Up To 40 MHz	
08/14/2015	Radiology	12-291	IEC	62127-2 Edition 1.1 2013-02	Ultrasonics -- Hydrophones -- Part 2: Calibration For Ultrasonic Fields Up To 40 MHz	

Step 5. Determine Content

- Must follow the requirements of the [guidance document](#) for your specific device.
(Top Priority)
- General requirement [Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510\(k\)s](#)

CONTENT OF 510(K) – 21 ELEMENTS

1. [Medical Device User Fee Cover Sheet \(Form FDA 3601\)](#)
2. [CDRH Premarket Review Submission Cover Sheet \(Form FDA 3514\)](#)
3. 510(k) Cover Letter
4. [Indications for Use Statement \(Form FDA 3881\)](#)
5. 510(k) Summary or 510(k) Statement (Form)
6. Truthful and Accuracy Statement (Form)
7. Class III Summary and Certification (Form)
8. Financial Certification or Disclosure Statement (Form FDA [3454](#), [3455](#))
9. Declarations of Conformity and Summary Reports (Standards)
10. Executive Summary (technology of the device & concise summary for any performance testing)

Content of 510(k) – 21 Elements (cont'd)

11. Device Description
12. Substantial Equivalence Discussion
13. Proposed Labeling (Guidance)
14. Sterilization and Shelf Life (Guidance)
15. Biocompatibility (Guidance)
16. Software (Guidance)
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing – Bench
19. Performance Testing – Animal
20. Performance Testing – Clinical
21. Other

3. 510(K) Cover Letter

- Type of 510(k) submission, abbreviated or traditional;
- Your device type in plain terms, i.e., By its common name;
- 510(k) submitter;
- At least one contact person, by name, title, and phone number;
- Your preference for continued confidentiality (21 CFR 807.95);
- Your recommended classification regulation;
- Device Class; Review Panel; Product code;
- Any FDA document numbers associated with prior formal correspondence with FDA, e.g., IDE, pre-submission, 510(k), PMA, request for designation (RFD), related to your device.

4. Indication For Use

- Prepare a Statement of Indications for Use as a separate page.
- The statement should include *specific indications, clinical settings, define the target population, anatomical sites*, etc.
- This statement must be consistent with your *labeling, advertising and instructions for use*.
- Once the review is complete, FDA will include the Indications for Use Statement with the Substantial Equivalence (SE) letter to the applicant and make it available to the public on the Internet.

5. 510K SUMMARY OR STATEMENT

Either provide Summary OR Statement

- If you choose to meet the conditions for a **510(k) Summary**,
 - it must be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.
 - Reference Guidance [The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notification \[510\(k\)\]](#). Section G
- If you choose to submit a **510(k) Statement**,
 - The regulation requires the specific statement as provided in [21 CFR 807.93](#).
 - Anyone may request a copy of the 510(k) [with patient identifiers, trade secret and confidential information deleted] from the applicant of record

510(k) Summary or Statement

Applicants Choice

Summary

- Separate Section – Begin and End on own page(s)
- Clearly identified as 510(k) Summary

510(k) Summary

- Safety & Effectiveness Information upon which 510(k) is based
- Sponsored and Predicate Device identifiers,
- Device description
- Description of Intended Use
- Non-clinical performance Tests Summary & Conclusion
- Summary of Clinical Tests, how results support SE, Conclusion
- Summary of SE Determinations

510(k) Summary

- Only contains information included in Body of 510(k)
- Not Contain unsubstantiated labelling claims
- Not Raw data
- Not Confidential or trade-secret info
- No patient identifiers

510(k) Statement

- Specific Statement must be included
- Signed by certifier
- Information must be fulfilled upon request within 30 days without charge
- Non-compliance is a prohibited act

[Link](#)

6. Truthful and Accurate statement

- All 510(k) submitters must include a statement certifying that all information submitted in the 510(k) is truthful and accurate and that no material fact has been omitted.
- The statement may be included in the 510(k) Cover Letter or may be on a separate page identified in the table of contents.
- Default Content:

I certify that, in my capacity as (the position held in company) of (company name), I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

7. Class III Summary and Certification

- For a device type classified into class III for not called for PMAs,
- The Class III Summary and Certification provide *a review of the risks and adverse events known* and associated with the general category of devices into which the proposed device falls.
- Default Content:

I certify that, in my capacity as (the position held in company) of (company name) that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety and/or effectiveness problems that have been reported for the (device name). I further certify that I am aware of the types of problems to which the (device name) is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety and/or effectiveness problems about the (device name) is complete and accurate.

9. Declarations of Conformity and Summary Reports

- Provide the information regarding any declarations of conformity to a standard or a summary report recommended in any relevant device-specific guidance.
- Refer to Guidance “Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices) ([here](#))

10. Executive Summary

- Description of the device, including the indications for use and technology;
 - sufficient to provide an overall understanding of the device.
- Device comparison table;
 - outline the differences and similarities between your device and the predicate.
- Summary for any performance testing in the submission.
 - discussion of how this comparison supports substantial equivalence.

11. Device Description

- Performance specifications
- Brief description of the device design requirements I
- Identify all models, all accessories or components
- Recommend to use diagrams, dimensions, tolerances, and/or schematics
- List of all patient contacting components and respective materials.

12. Substantial Equivalence (SE)

The device specifications are the basis for the comparison of features between the new and the legally marketed device to which compared (predicate device).

- **Indications for use;**
 - Target population;
 - Anatomical sites;
 - Where used (hospital, home, ambulance, etc);
- **Technology**
 - Design;
 - Materials
 - Energy used and/or delivered;
 - Human factors;
 - Compatibility with the environment and other devices
- **Performance Specifications, including testing**
 - Specifications
 - Biocompatibility
 - Sterility
 - Electrical safety
 - Mechanical safety
 - Chemical safety
 - Thermal safety
 - Radiation safety

(Example and recommendation, not a exhaustive list)

Example - Format of SE comparison

No.	Items	Subject device	Predicate device	Same/Difference Interpretation
1	K number			-
2	Manufacturer			-
3	Device name			-
4	Classification, regulation number, product code			
5	Intended use/IFU			
...	...			
...	Electrical safety	IEC 60601-1 Conformance	IEC 60601-1 Conformance	Same because...

DESCRIPTIVE COMPARISON TO LEGALLY MARKETED DEVICE(S)

Discussion of similarities/differences

- Elaborate on similarities if appropriate
- Justify differences with supporting rationale, and/o testing results.

Closing paragraph for Substantial Equivalence

13. Proposed Labeling

- Prepare a labeling section to include copies of all proposed labels, labeling, package inserts, service manuals, instructions for use, advertising and/or promotional materials
- Labeling information
 - Manuals, instructions
 - Indications for use, contraindications, warnings, precautions
 - Care, cleaning, disinfection, sterilization
 - Literature references
 - Promotional material
 - Advertising material

Labels and Labeling Information

- Copies of labeling for the predicate device(s) is recommended. Labeling guidance is provided below
 - [General Device Labeling](#)
 - [Device Labeling Guidance #G91-1 \(Blue Book Memo\)](#) – Definition of Content
 - [Guidance on Medical Device Patient Labeling;](#)

Labels and Labeling Information

- Under **no circumstances** may the labeling of any medical device bear
 - firm's facility registration number,
 - device listing number,
 - 510(k) premarket notification clearance or
 - premarket approval number.
- Any representation that creates an impression of official **approval by FDA** related to these numbers will **misbrand** the device.
- Any phrase, such as "FDA approved", which connotes FDA approval of the device, is also prohibited under section 301(l) of the FD&C Act.

14. Sterilization and shelf life

- Sterilization and validation method (not raw data)
- Sterility assurance level (SAL 10^{-6})
 - ETO method: maximum levels of ethylene oxide
 - Radiation method: radiation dose to achieve sterility
- Description of packaging to maintain sterility (not raw data)
- Shelf life for the device, should be supported by appropriate bench tests and/or sterilization (packaging) validation.
 - Realtime test
 - Acceleration test

15. Biocompatibility

- For materials that come into contact with patient or user
 - Exact identification and composite of materials
 - Explicitly state differences to predicate device
- Guidance document: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

16. Software

Determine level of concern (LOC)

- Minor, moderate, major
- Sometimes indicated in Guidance Document
- 510(k) Summaries for similar devices
- “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.		
Software Description	A summary overview of the features and software operating environment.		
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.		
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	The complete SRS document.	
Architecture Design Chart	No documentation is necessary in the submission.	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	
Software Design Specification (SDS)	No documentation is necessary in the submission.	Software design specification document.	
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.		
Software Development Environment Description	No documentation is necessary in the submission.	Summary of software life cycle development plan, including a summary of the configuration management and	Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
		maintenance activities.	configuration management and maintenance plan documents.
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.	Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.
Revision Level History	Revision history log, including release version number and date.		
Unresolved Anomalies (Bugs or Defects)	No documentation is necessary in the submission.	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.	

17. Electromagnetic Compatibility and Electrical Safety

- Pay attention to updated Recognized Consensus Standards.
 - IEC 60601-1 series
 - IEC 60601-1-2 (EMC)
- Note: There is “extent of recognition”

18-20. Performance Testing

- Most 510(k)s will include some type of performance data.
- The extent of performance data will depend on the complexity of the device and its intended use and indications.
- Help demonstrate SE of your device to predicate device.
- Search the [Guidance Document](#) database to determine if guidance documents are available for your type of device.
- Recommend to consult FDA through [Pre-Submission Application \(Q-Sub\)](#)

18. Performance Testing – Bench

- Guidance – Content and format of non-clinical bench performance testing (exclude: Biocompatibility evaluation, reprocessing or sterilization validations, human factors, software V&V).
- Testing report should include:
 - Test performed
 - Objective of the test
 - Description of test methods
 - Test Sample Information
 - Sample Size
 - Test Methods
 - Pass/fail criteria.
 - Data analysis plan
 - Test Results
 - Data
 - Data analysis
 - Protocol deviations
 - Discussion/Conclusions

19. Performance Testing – Animal

- First priority - Device-specific Guidance document
- Considering the draft [guidance “General Considerations for Animal Studies for Medical Devices”](#)
- The description of test protocols should identify the:
 - objective of the test
 - test articles used in the test
 - test methods and procedures (including any specific test conditions)
 - study endpoint, i.e., the specific parameter measured
 - pre-defined acceptance or pass/fail criteria.
- The description of test results should identify the:
 - list the specific animal tests conducted
 - describe each test protocol
 - summarize the results
 - describe your analysis
 - discuss your conclusions

20. Performance – Clinical

- First priority : Device-Specific Guidance
- Should include following information:
 - objective of the test
 - test methods and procedures (including any specific test conditions)
 - study endpoints (usually both safety and effectiveness)
 - statistical methodology used.
- Discuss the study results, analyses performed (including statistical, as appropriate), and conclusions

Example: Complete Submission Dossier

-  001_MUDF Cover Sheet.pdf
-  002_FDA Form 3514.pdf
-  003_FDA Form 3654.pdf
-  004_FDA Form 3674.pdf
-  005_Table of Contents.pdf
-  006_510(k) Cover Letter.pdf
-  007_510(k) Summary.pdf
-  008_Indications for Use.pdf
-  009_Truthful and Accurate Statement.pdf
-  010_Executive Summary.doc.pdf
-  010_Executive Summary.pdf
-  011_General Device Description.pdf
-  012_Substantial Equivalence Comparison.pdf
-  013_Acoustic Output Report.pdf
-  014_Software,Firmware Information.pdf
-  015_Software Hazard Analysis.pdf
-  016_Software Requirement Specification.pdf
-  017_Software Design Specification.pdf
-  018_Software Verification and Validation.pdf
-  019_General Clinical Safety & Effectiveness.pdf
-  020_Patient Contact Materials and Compatibility.pdf
-  021_Proposed Labeling.pdf
-  022_User Manual _Basic.pdf
-  023_User Manual _Advanced.pdf
-  024_EM Test Report.pdf
-  025_Electrical Safety Test Report.pdf
-  026_(IEC 60601-2-37) Test Report.pdf
-  027_Predicate Device 510(k) Summary.pdf
-  028_Predicate Device Basic Operation Manual.pdf
-  029_Predicate Device Advanced Operation Manual.pdf
-  030_Checklists.pdf

Refuse to Accept (RTA guidance)

[510k Checklist](#) website

Contains Nonbinding Recommendations

Refuse to Accept Policy for 510(k)s

Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 21, 2019.

Document originally issued on May 20, 1994.

This document supersedes "Refuse to Accept Policy for 510(k)s" issued January 30, 2018.

For questions about this document regarding CDRH-regulated devices, contact the 510(k) Staff at 301-796-5640.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.



U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

1

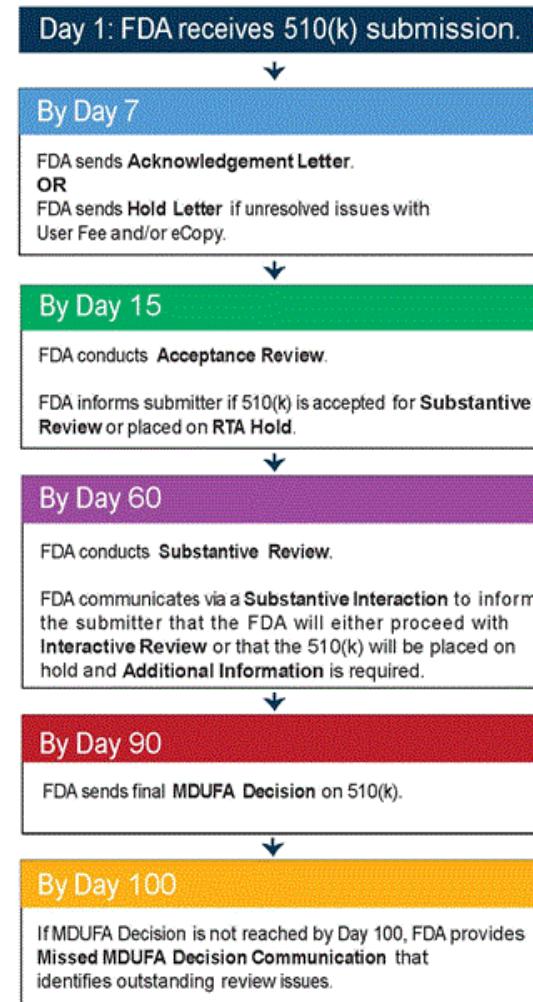
Step 6. Assemble the Submittal

- A specific format for the submission is required.
- Failure to the format guidelines will delay your evaluation of your submittal
 - Table of Contents
 - Numbered Pages
 - Use numbered or lettered tabulation sheets to separate the sections in the 510(k)
 - Use 8.5" x 11" (21.5 cm x 27.8 cm) 3-hole punched, white paper only
 - Place the 510(k) in an inexpensive jacket or non-permanent binding.
 - eCopy format
 - Two copies of your 510(k). One must be submitted in electronic format

FDA Review and Common Deficiencies

USFDA 510(k) Review Timeline

- **Acknowledgment Letter**
- **Acceptance Review**
- **Substantive Review**
- **AI Letter**
- **510(k) Decision Letter**



Note:
Days are Calendar Days.

Common Deficiencies

- Human Factor Engineering
 - Conduct testing outside US
 - Inappropriate sample size and group
 - Inadequate testing design
- Biocompatibility
 - Missing risk analysis
 - Inadequate testing method
 - Insufficient testing items
- Software Documentation
 - Inadequate software classification – not follow software Level of Concerns (LOC)
 - Missing risk management
- Cybersecurity
 - Insufficient evidence for cybersecurity
 - Missing post-market cybersecurity plan

Common Deficiencies

- EMC requirements
 - Inadequate testing methods
- Testing
 - Missing testing items without rationales
 - Only perform IEC 60601-2-XX, Essential performance, insufficient to support device effectiveness
- Labeling
 - Contains information which is not consistent with content in other documents
- Others
 - Incomplete testing items, such as shipping testing, packaging testing, biocompatibility, mechanical testing, shelf life testing, etc,

Current trends- Human Factor and Cybersecurity

Human Factor Engineering / Usability Engineering



Helping clients develop safe, usable, and satisfying products



EMERGO
by UL

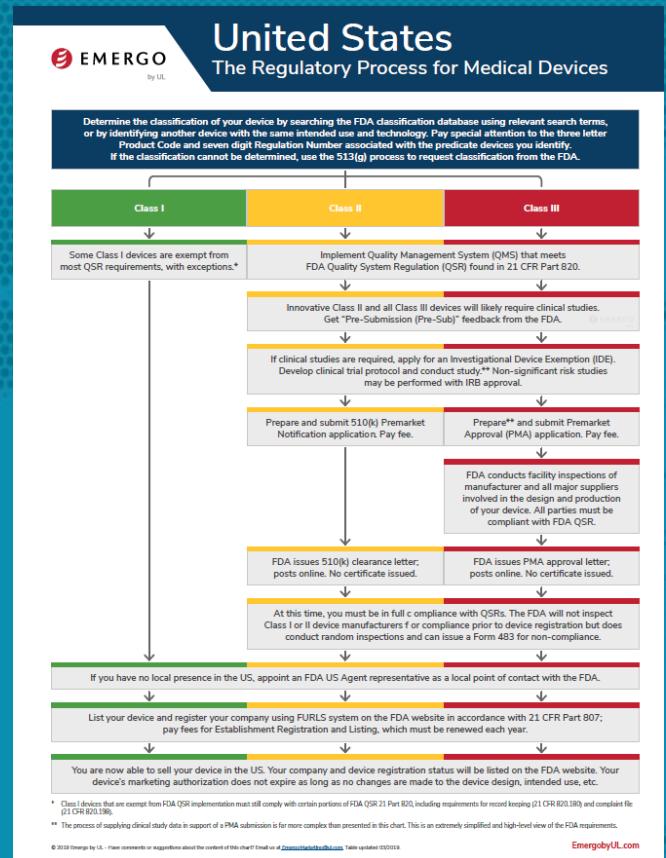
Human Factors Research & Design
Reduce your business risk and accelerate innovation for a worldwide market.

Human factors examines the relationship between human beings and the systems they use, focusing on improving efficiency and ease of use with the goal of minimizing errors. Our consulting team has deep experience in the medical device and combination product domains.

Cybersecurity and Software validation

- UL 2900-1 and UL 2900-2-1 are recognized consensus standards in USFDA, and National Standard of Canada
- Compliance with UL 2900-1 and UL 2900-2-1 provide evidence of compliance with USFDA current guidance

Time-to Market and Cost



Download at:
<https://www.emergobyul.com/resources/usa-process-chart>

Time to Market

Device classification in the USA →	Class I*	Class II	Class III**
How long you should expect to wait after submission until approval is granted. ¹	1 month	6-9 months	18-30 months
Validity period for device approval. ²	Does not expire	Does not expire	Does not expire
Complexity of the registration process for this classification. ³	Simple 2	Complex 4	Simple Complex 5
Overall cost of gaining regulatory approval. ⁴	Low 1	High 3	Low High 5

Cost Estimation

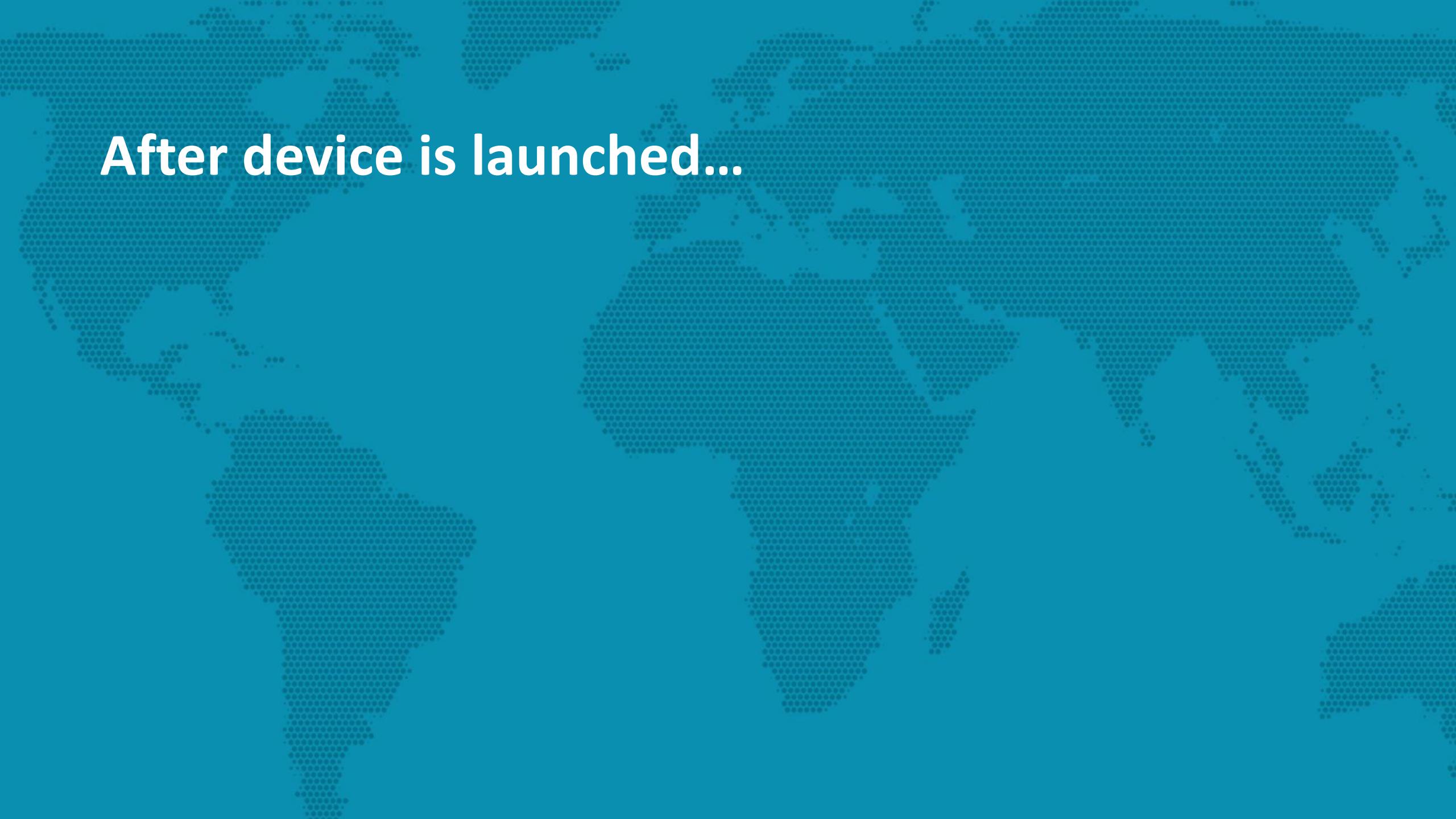
Testing and Documentations	USD (\$)	Application – Related Fee *	USD (\$)
IEC 60601 Series	(Varies) \$ 8,000 - \$ 40,000	510 (k) Application Fee (Either Standard or Small Business)	Fee: (Standard) \$ 10,953 ** Fee (Small Business): \$ 2,738
ISO 10993-1 Series	(Varies) \$ 5,000 - \$ 80,000		
Performance Testing	(Varies) \$ 8,000 - \$ 40,000		
Others (Human Factor, Cybersecurity, etc.)	(Varies) \$ 20,000 - 100,000	***Annual Establishment Registration Fee:	\$4,884
Shelf life, Packaging, Shipping testing	(Varies) \$ 5,000 - \$ 20,000		

Estimation for reference only and may vary based on device and testing items.

* :Update every FY year

** :Apply Small Business Certificate first

*** :Fee occurs once organization registers



After device is launched...



FDA Form 483 Frequently Asked Questions

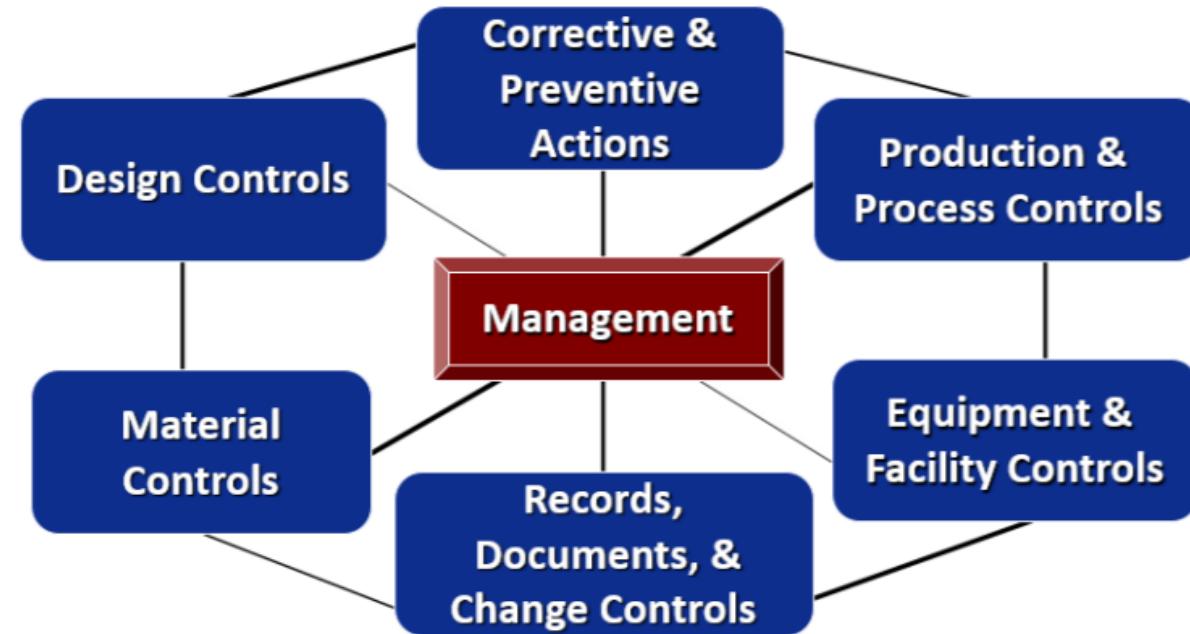
[SHARE](#)[TWEET](#)[LINKEDIN](#)[PIN IT](#)[EMAIL](#)[PRINT](#)

Q: When is an FDA Form 483 issued?

A: An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant. Observations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.

Quality Management System Implementation

- **Quality System Regulation (QSR)** found under **21 CFR 820**
- Purpose is to govern methods used in, and facilities/controls used for:
 - Design
 - Manufacture
 - Packaging
 - Labeling
 - Storage
 - Installation
 - Servicing
- Subject to **FDA inspection**

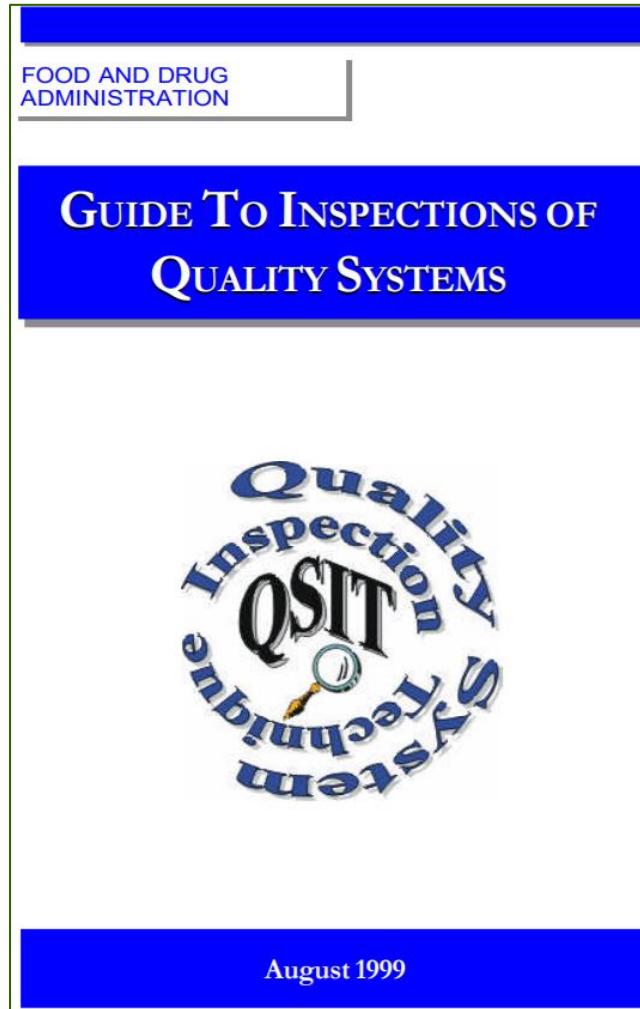


ATTENTION !

- All manufacturers (including specification developers) of Class II and III devices and select Class I devices are required to follow design controls during the development of their device.
- The holder of a 510(k) must have design control documentation available for FDA review during a site inspection.
- Any changes to the device specifications or manufacturing processes must be made in accordance with the Quality System regulation (21 CFR 820) and may be subject to a new 510(k).

QUALITY SYSTEM – CFR 820

1. Be Prepared
2. Know what FDA expects



What to Expect During a US FDA Medical Device Inspection
How the QSR inspection is structured, creating a pre-audit checklist, and how to follow up on findings

August 2016

The infographic features a world map background with a "US" icon. It includes three small images: a person writing, the New York City skyline with flags, and a woman in a suit looking at documents.

Take-home Message

- Conduct regulatory research before heading into 510(k)
- Comply with Guidance !
- Provide complete information rather than explanation in AI stage.
- Keep up with regulatory changes

References

- **510(k)** - <https://www.fda.gov/medical-devices/premarket-notification-510k/how-prepare-traditional-510k>
- **513(g)** - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic>
- **Pre-submission** - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>
- **Refuse to Accept** - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks>
- **Device Labeling** - <https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling>
- **FY 2019 MDUFA User Fees** - <https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/fy-2019-mdufa-user-fees>

References

- **Use of ISO 10993-1** - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- **Human Factor** - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices>
- **Home Use Device** - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-devices-intended-home-use>
- **Non-clinical Testing** - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket>
- **Cybersecurity Premarket** - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>
- **Draft – Cybersecurity Premarket:** - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices>
- **Cybersecurity Postmarket** - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices>

Questions?

Thank you for your time and attention

Contact Information:

Terri Chin | Sales Manager
Email: Terri.Chin@ul.com

Robert Teng | Business Development
Email: Robert.Teng@ul.com

Tim Lin | Sr. RA/QA Consultant
Email: Tim.Lin@ul.com

The screenshot shows the homepage of the RADAR newsletter. At the top, there's a header with the word "RADAR" in large red letters, followed by "Global Medical Device Regulatory Updates" and the EMERGO logo. Below the header is a navigation bar with links for SERVICES, VIDEOS, WHITE PAPERS, CHARTS, REGULATIONS, BLOG, and CONTACT. The main content area starts with a greeting "Hello Alexis!" and a brief summary of the latest edition. It highlights the UK's redefinition of Own Brand Labeling (OBL) as "virtual manufacturing" and covers Brazilian regulatory updates. Below this is a section titled "UK Medical Device Regulators Introduce 'Virtual Manufacturing' to Replace OBL" with a link to "Read More". Another section titled "Medical Device Vigilance Reporting" includes a thumbnail of a whitepaper cover and a "EMAIL PDF TO ME" button.

Our Areas of Expertise

-  Classification & RA Strategy
-  Device/IVD Registration
-  In-Country Representation
-  Internal/Supplier QMS Audits
-  ISO 13485:2016 Transition
-  EU MDR/IVDR Compliance
-  Clinical Consulting Support

<https://www.emergobyul.com/newsletters>