Foundations of Medical Device Regulation in a World of Change

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

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How do all the regulatory pieces fit together?

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Learning Objectives

- Define a medical device

- Describe device classification and regulatory controls

- Review premarket submission types

- Differentiate preparing and sending a premarket submission

Is My Product a Medical Device?

Medical Device Definition

1. Is an article, an item, such as, not limited to:

- Instrument
- Machine
- Implement

- Implant
- Apparatus
- In vitro reagent

Note: Software can be a medical device, but there are some exceptions per Section 520(o) of the FD&C Act.

Medical Device Definition

2. Intended for use:

   – in diagnosis of disease or other conditions

   – or in the cure, mitigation, treatment, or prevention of disease

   – or intended to affect the structure or any function of the body

Medical Device Definition

3. Does NOT achieve its primary intended purposes through chemical action or dependent on being metabolized

Medical Device Definition

- [21 U.S.C. 321(h)](#)

- [How to Determine if Your Product is a Medical Device](#)

- [CDRH Learn Module: Is My Product a Medical Device?](#)

CDRH Learn

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Welcome to CDRH Learn! CDRH Learn is our multi-media educational resource, featuring learning modules that address medical device and radiation emitting product laws, regulations, guidances, and policies, across the entire product life cycle. These modules provide industry with information that is comprehensive, interactive, and easily accessible. Modules are provided in various formats, including videos, audio recordings, and slide presentations.

Tips for Viewing Modules
Modules should be compatible with most devices (computers, tablets, smart phones). We recommend you use Mozilla Firefox or Google Chrome to view modules. If you encounter a viewing error, we suggest you try another browser.

Start Here/The Basics! (Updated Module 10/16/2023)
MDUFA Small Business Program, Registration and Listing   ⌄

How to Study and Market Your Device - (Updated 11/20/23)
510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification   ⌄

Postmarket Activities
Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization   ⌄

In Vitro Diagnostics - (Updated 12/19/23)
IVD Development, CLIA, and Virtual Town Hall Series   ⌄

Unique Device Identification (UDI) System   ⌄

Specialty Technical Topics - (Updated 4/26/24)   ⌄

Radiation-Emitting Products   ⌄

510(k) Third Party Review Program (for Third Party Review Organizations)   ⌄

Industry Basics Workshop Series   ⌄

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Knowledge Check
Which of these is <u>NOT</u> a medical device?

A

B

C

D

What classification and regulatory controls apply to my device?

Medical Device Classification

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Categorized by risk

- Class I – lowest risk

- Class II – moderate risk

- Class III – highest risk

Using Databases

- [Product Classification Database](#)

- [Establishment Registration & Device Listing Database](#)

- [Medical Device Databases](#)

Product Classification

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 Elligible	[▾]
Implanted Device	[▾] Life-Sustain/Support Device [▾]	Device Class	[▾]
Summary Malfunction Reporting	[▾]		

Go to Quick Search   Clear Form   search

Medical Device Regulations

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- Ensure safety and effectiveness of medical devices

- Provide consistent, risk-based requirements

- General, Special and PMA controls

Medical Device Classification

- [Classify Your Medical Device](#)
- CDRH Learn:
- [Device Classification](#)
- [FDA's Regulation of Medical Devices](#)

Which premarket submission does my device require?

Premarket Notification (510(k)) Exempt

- Lowest risk devices

- Can be Class I or II devices

- General controls, unless regulation states otherwise

510(k) Required

- Moderate risk devices

- Can be Class I or II devices

- Demonstrate the device is substantially equivalent to a predicate device

- General and Special controls, as defined by regulation

Premarket Approval (PMA)

- Highest risk devices

- Class III devices

- Provide valid scientific evidence to assure safety and effectiveness for intended use

- General and PMA controls

De Novo

- Novel devices; No predicate device exists

- Results in reclassification to Class I or II

- Controls: General or General + Special

Humanitarian Device Exemption (HDE)

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- Requires Humanitarian Use Device (HUD) designation first

  – For rare diseases and conditions

  – Demonstrates no significant risk and probable benefit

- No legally marketed device for same intended use granted under:

  – 510(k), PMA, De Novo

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Organizing All the Possibilities

Increased Risk

Class	Potential Harm	Controls	Submission Type(s)
I	Present minimal potential for harm	General	510(k) Exempt 510(k) De Novo (very few)
II	Higher risk than Class I devices	General and Special	510(k) Exempt 510(k) De Novo (few)
III	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury	General and PMA	PMA

How do I prepare a premarket submission to the FDA?

Preparing Your Premarket Submission

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- electronic Submission Template And Resource (eSTAR)

    - Interactive template

    - Required for ALL 510(k) premarket submissions

    - Voluntary for De Novo, PMA

eSTAR

Application/Submission Type

Application Jurisdiction	◉ US FDA ◯ Health Canada	?

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if a legible English (i.e. not broken English) translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose	◉ Premarket Notification 510(k) ◯ De Novo ◯ Premarket Application PMA	?

Show Application Introduction

Application Type *(Choose Abbreviated if you are submitting a Safety & Performance based submission.)*	◉ Traditional ◯ Abbreviated ◯ Special	

Show Application Type Introduction

Application Sub-Type *(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*	◉ New Application/Submission ◯ Additional Information	?

eSTAR

Cover Letter / Letters of Reference

| Add Attachment | Attach your Cover Letter | ? |
| Add Attachment | Attach any Letters of Reference | ? |

Applicant Information   ?

Contact

Title [▾] First Name [   ] Last Name [   ]

Email [   ] Phone Number [   ]

Occupation Title [   ]

Company

Company Name [   ]

Address - Line 1 [   ]

Address - Line 2 [   ]

City [   ] State [ ] Zip [   ] Country/Region [United States ▾]

| Add Correspondent/Consultant |

Pre-Submission Correspondence & Previous Regulator Interaction

Are there prior related submissions or regulator interaction for the subject device(s)? [▾] ?

Standards   ?

| Add Standard | Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. A recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators request standards information be attached. |

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Preparing Your Premarket Submission

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- electronic copy (eCopy)

  - This is not an electronic submission

  - Previous paper version in an electronic format

  - NO 510(k)s

  - Required for an HDE

Premarket Submissions

- [Premarket Submissions: Selecting and Preparing the Correct Submission](#)
- Entire section at CDRH LEARN How to Study and Market Your Device

How do I submit a premarket submission to the FDA?

Sending Your Premarket Submission

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- CDRH Customer Collaboration Portal (CCP)

  - Online submission - Document Control Center (DCC)

  - Anyone can register an account

  - Accepts eSTAR and eCopy formats

  - Required for ALL 510(k) premarket submissions

Welcome, Kendra Holter

Your premarket medical device reviews

0 Records

▼ Active reviews only (default)   👁 Fields

ID ❓	Received date	Progress	Type	Track	Goal date	Days	More info

You don't have any active reviews or reviews closed in the last 30 days.

Your sent submissions

0 Records

▼ Recent submissions only (default)

You haven't sent anything yet. Send a submission, or select + in the main navigation.

Send your submission before 16:00 ET on a business day for us to process it the same day.

Talk to us

What did you think of this experience? Share your thoughts at CCP@fda.hhs.gov.

If you just sent a submission, we will send you an email confirming this upload soon. We will also send the Official Correspondent an email update about their submission's status within 1 business day. If these emails are not received, please contact CCP@fda.hhs.gov.

Need more help? Visit our self-help or tell us what you need at CCP@fda.hhs.gov.

Do you research website data security? Read the HHS Vulnerability Disclosure Policy.

Sending Your Premarket Submission

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- Mail to Document Control Center (DCC)

  - Postal service

  - Carrier service

  - Will take more time than use of CCP

Tracking Your Premarket Submission

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- Through the CCP

  - By official correspondent or designated delegates only

  - ALL 510(k) and De Novo

  - Not yet for PMAs

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Premarket Submissions

- [Send and Track Medical Device Premarket Submissions Online: CDRH Portal](#)

Knowledge Check

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True or False

eSTAR is a portal I will use to submit my 510(k) premarket submission when complete.

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Am I allowed to market my device once my premarket submission is cleared or approved?

Examples of General Controls

Control	Regulation (21CFR Part)
Labeling	801
Medical Device Reporting	803
Establishment Registration	807
Device Listing	807
Quality System	820
Adulteration	FD&C Act 501
Misbranding	FD&C Act 502

Regulatory Controls

- [General Controls for Medical Devices](#)
- [Class II Special Controls Documents](#)

Resources

FDA

Slide Number	Cited Resource	URL
8	U.S.C. 321(h)	uscode.house.gov/view.xhtml?req=(title:21%20section:321%20edition:prelim)%20OR%20(granuleid:USC-prelim-title21-section321)&f=treesort&edition=prelim&num=0&jumpTo=true
8	How to Determine if Your Product is a Medical Device	www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device
8	CDRH Learn Module: Is My Product a Medical Device?	fda.yorkcast.com/mediasite/Play/e0eec5f6ee3d4947a70fcedef32993f71d
14	Product Classification Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm
14	Establishment Registration & Device Listing Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Resources

FDA

Slide Number	Cited Resource	URL
14	Medical Device Databases	www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
17	Classify Your Medical Device	www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
17	Device Classification	fda.yorkcast.com/mediasite/Play/17792840509f49f0875806b6e9a1be471d
17	FDA's Regulation of Medical Devices	fda.yorkcast.com/mediasite/Play/884aea9662174dea8ef4df68988b86981d

Resources

Slide Number	Cited Resource	URL
30	Premarket Submissions: Selecting and Preparing the Correct Submission	www.fda.gov/medical-devices/how-study-and-market-your-device/premarket-submissions-selecting-and-preparing-correct-submission
36	Send and Track Medical Device Premarket Submissions Online: CDRH Portal	www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal
40	General Controls for Medical Devices	www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices
40	Class II Special Controls Documents	www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-documents

Summary

- Medical devices are defined in Federal Law and consists of both the product and intended use

- Devices have specific classifications and regulatory controls

- FDA has different types of premarket submissions based on how the device is regulated

- You have specific means to prepare and send your premarket submission to FDA

Questions

Your Call to Action

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1. Determine if your product is a medical device.

2. Classify your device identifying the regulatory controls that will apply.

3. Select the appropriate premarket submission, prepare, and submit according to resources provided.

4. Ensure compliance with all regulatory requirements for your device, even exempt devices have applicable regulations.