How is My Medical Device Classified?

CDR Kimberly Piermatteo, MHA
Consumer Safety Officer
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

How to Use this Presentation

1. **How is My Medical Device Classified?**
2. Case Study: How is My Medical Device Classified?

Learning Objectives

1. Explain how medical devices are classified
2. Discuss the regulatory requirements for medical devices
3. Discuss classification determination methods
4. Identify ways to request additional assistance

Medical Device Classes and Applicable Regulatory Requirements

Device Risk

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Class

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Extent of Regulatory Controls

Classes of Medical Devices

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption	Percent Devices in Class*
I					
II					
III					

Classes of Medical Devices

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I	Lowest	Present minimal potential for harm			
II	Moderate	Higher risk than Class I devices			
III	Highest	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury			

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What are “Regulatory Controls”

- General, Special or Premarket Approval
- Apply to a particular device type
- Generally broad, but may be specific
- Describe the appropriate level of regulatory oversight to ensure reasonable safety and effectiveness

Resource:

- Regulatory Controls: www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls

Classes of Medical Devices

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption	Percent Devices in Class*
I	Lowest	Present minimal potential for harm	General		
II	Moderate	Higher risk than Class I devices	General and Special (if available)		
III	Highest	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury	General and PMA		

Examples of General Controls

Control	Regulation (21 CFR Part)	Brief Description
Adulterated	FD&CA 501	Provide device not proper for use
Misbranded	FD&CA 502	Provide false or misleading labeling
Labeling	801	Provide information for users
Medical Device Reporting	803	Report device-related injuries and deaths
Establishment Registration	807	Register company with FDA
Device Listing	807	Identify devices with FDA
510(k) Premarket Notification	807	Substantially equivalent to legally marketed device
Quality System/Good Manu. Practices	820	Ensure safe and effective finished devices

FD&CA = Food, Drug and Cosmetic Act; CFR = Code of Federal Regulation

Examples of Special Controls

- Special Labeling
- Design Characteristics or Specifications
- Performance Standards
- Premarket Data Requirements
- Guidance Documents

Premarket Approval

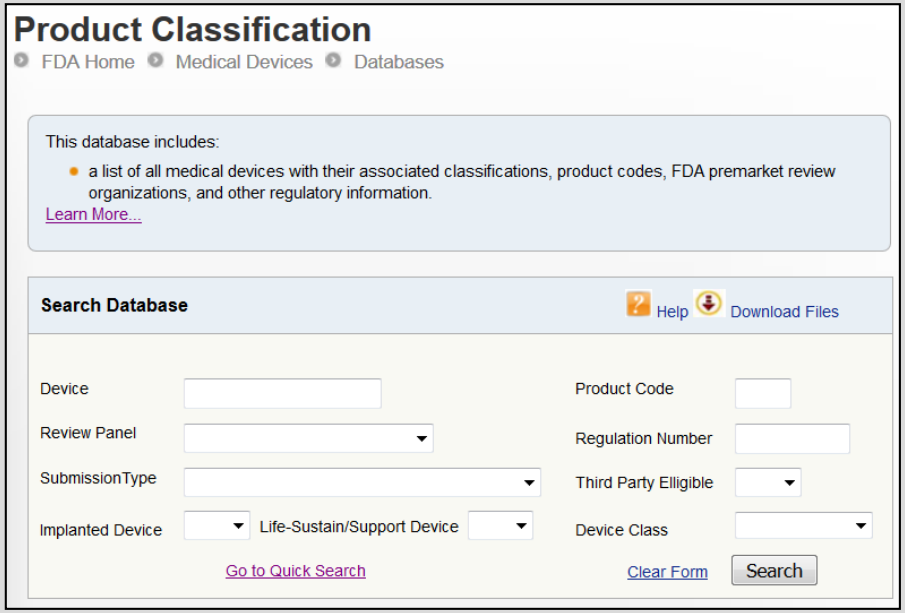
- Typically for life supporting or life sustaining devices
- General and Special Controls are insufficient to provide reasonable assurance of safety and effectiveness
- 21 CFR 814: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=814

Classes of Medical Devices

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption	Percent Devices in Class*
I	Lowest	Present minimal potential for harm	General	510(k) 510(k) Exempt (Most are exempt from 510(k))	
II	Moderate	Higher risk than Class I devices	General and Special (if available)	510(k) 510(k) Exempt	
III	Highest	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury	General and PMA	PMA	

FDA Product Codes

- Three letter codes (e.g., CBK, FRN)
- Used by FDA to identify and track similar medical devices



Product Classification Database:
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

Regulations and Product Codes

Same Regulation Number (21 CFR 870.1875)

Four Different Product Codes for Specific Device Types

Device Type	Class	510(k) Exempt?	Product Code
Manual Stethoscope	1	Yes	LDE
Electronic Stethoscope	2	No	DQD
Cranial Sound Monitor	2	No	QBE
Lung Sound Monitor	2	Yes	OCR

Classes of Medical Devices

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption	Percent Devices in Class*
I	Lowest	Present minimal potential for harm	General	510(k) 510(k) Exempt *93% are exempt from 510(k)	35%
II	Moderate	Higher risk than Class I devices	General and Special (if available)	510(k) 510(k) Exempt	53%
III	Highest	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury	General and PMA	PMA	9%

***3% of devices are Unclassified**

Classification Determination Methods

Classification Determination Methods

1. Search for an appropriate product classification

2. Search for a similar device by clearance or approval

3. Search for a similar device by device listing

Classification Determination Methods

1. Search for an appropriate product classification

- Product Classification Database: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm
- Search for FDA product codes
- Most common method

Classification Determination Methods

2. Search for a similar device by clearance or approval

- 510(k) Clearance Database: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- Premarket Approval (PMA) Database: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
- De Novo Database: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm

Classification Determination Methods

3. Search for a similar device by device listing

- All establishments currently marketing a medical device must be registered and list their devices ⇨ A General Control
- Establishment Registration and Device Listing Database: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Additional Assistance

Division of Industry and Consumer Education

- Contact the **Division of Industry and Consumer Education (DICE)**
  - Phone: 1-800-638-2041
  - Email: dice@fda.hhs.gov

Note: Responses are not classification decisions and do not constitute FDA clearance or approval for commercial distribution

513(g) Request

- Appropriate when a **formal product classification** is requested
- FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act:

  www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic

Note: Responses do not constitute FDA clearance or approval for commercial distribution

Summary

- Medical devices are **classified based on risk**
- The **risk** of the device determines the **extent of regulatory controls**
- The class and regulatory requirements for a medical device may be determined by **searching FDA's public databases**

Resources

Slide Number	Cited Resource	URL
1	How to Classify Your Medical Device	www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
8	Regulatory Controls	www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls
13	Class I/II Exemptions	www.fda.gov/medical-devices/classify-your-medical-device/class-i-ii-exemptions
13	Premarket Notification 510(k)	www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k
13	Premarket Approval	www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma

Resources

Slide Number	Cited Resource	URL
14	Medical Device Classification Product Codes - Guidance for Industry and Food and Drug Administration Staff	www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-classification-product-codes-guidance-industry-and-food-and-drug-administration-staff
14, 19	Product Classification Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm
15	Code of Federal Regulations (CFR) Search	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
20	510(k) Clearance Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
20	Premarket Approval (PMA) Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

Resources

Slide Number	Cited Resource	URL
20	De Novo Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm
21	Establishment Registration and Device Listing	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
24	FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act	www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic

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2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: DICE@fda.hhs.gov
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4:30 pm ET)

Your Call to Action

- Evaluate the **risk** of your device to determine the **class** and applicable **regulatory controls**
- Familiarize yourself with **different classification determination methods**
- View CDRH Learn Module - **Case Study: How is My Medical Device Classified?**


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