Demystifying Medical Device Regulation

FDA Small Business Regulatory Education for Industry (REdI)

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Common Questions

Is my product a device?

Do I have to register?

What else?

Postmarket?

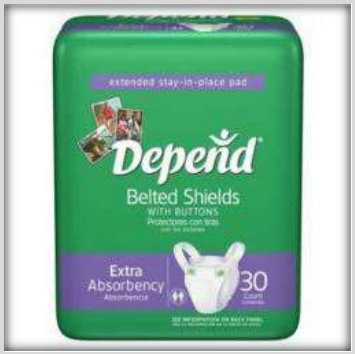
Learning Objectives

- Define medical device
- Describe FDA's regulatory controls
- Identify steps to bring a new product to market
- Locate available resources

Common Question

Is my product a device?

powered wheelchair: device



Protective garment: device???

Medical Device Definition

Medical Device

- Intended for:
  - **diagnosis** of disease or other conditions
  - or **cure, mitigation, treatment, or prevention** of disease
  - or to affect the **structure** or any **function** of the body

Medical Device (continued)

- Does **NOT achieve** its primary intended purposes **through chemical action** or dependent on being **metabolized**

- Does **NOT** include **certain software functions** excluded pursuant to section 520(o).

Resources

- Medical Device Definition: Section 201(h) of the Food, Drug & Cosmetic Act

  (FD&C Act; or 21 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

Resources

- *How to Determine if Your Product is a Medical Device* webpage:
  www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device
- CDRH Learn Module: *Is My Product a Medical Device?*
  fda.yorkcast.com/webcast/Play/884aea9662174dea8ef4df68988b86981d

Knowledge Check

A

Which is a medical device?

A. Personalized comfort bed
B. Air-fluidized bed
C. Neither
D. Both

B

Regulatory Controls

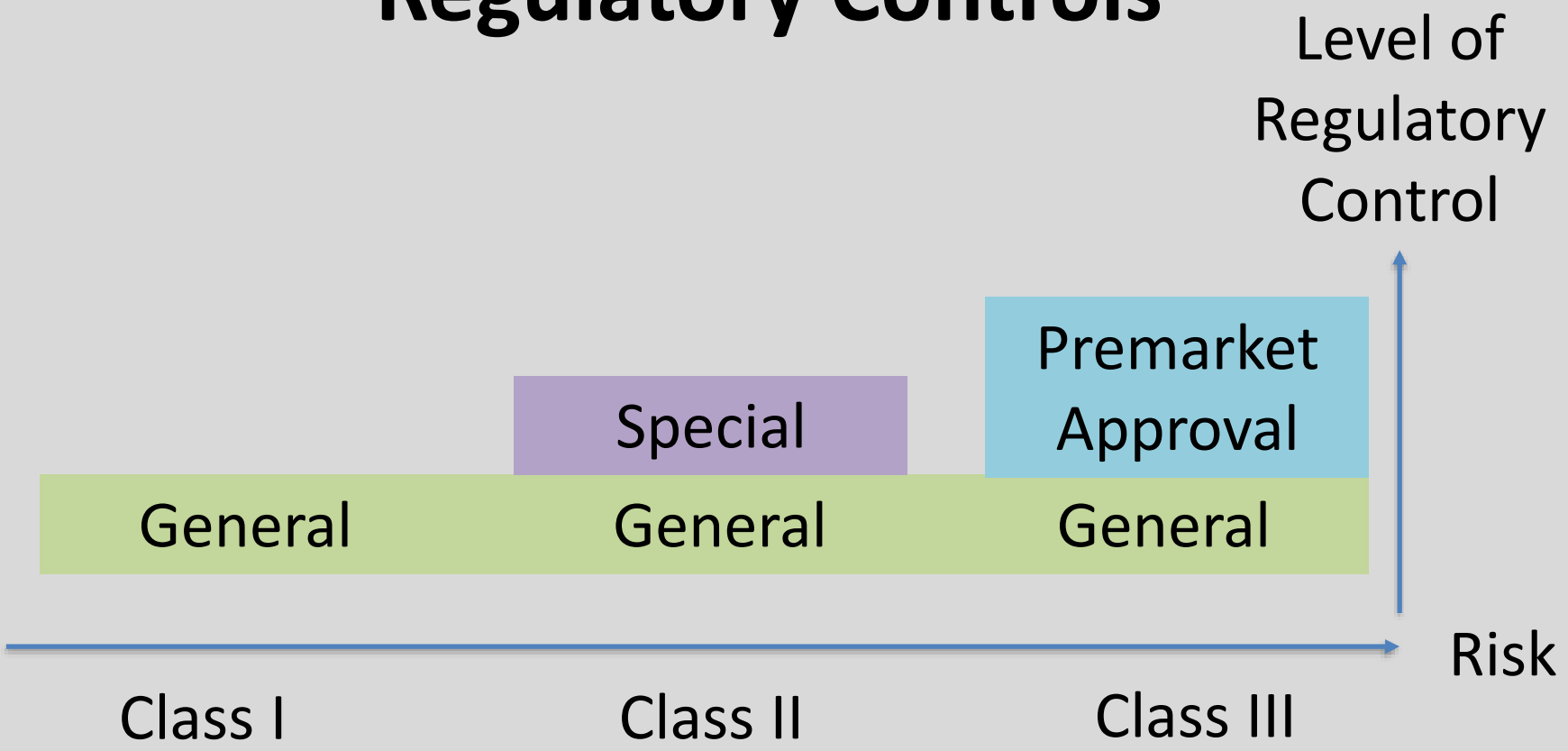
CDRH

- **CDRH regulates medical devices and radiation-emitting products**
  - Ensure safety and effectiveness of medical devices

Regulatory Controls

- Provide **consistent requirements**
- Appropriate **level** of regulatory oversight
- Based on the level of **risk**

Regulatory Controls



General Controls

- All medical devices, unless exempted by regulation
- Examples:
  - **Registration** of manufacturing facilities
  - **Listing** of device types
  - **Quality system (QS)**
  - **Labeling**
  - Premarket notification **510(k)**

Common Questions

Registration is a general control

Do I have to register?

What else?

Listing … QS … Labeling … 510(k) …

Common Questions

MDR …
Complaints …
Recalls …
Tracking …

Postmarket?

Special Controls

- Apply when General Controls are insufficient
- Examples:
  - Special **labeling** requirements
  - Mandatory **performance standards**
  - **Postmarket** surveillance
  - Premarket **data** requirements

Common Questions

Special Controls

- Classification Regulation
- *Class II Special Controls Documents* webpage

What else?

Postmarket?

Premarket Approval

- Market pathway for
  highest risk (Class III) devices

- Reasonable assurance:
  – safety and effectiveness

Common Questions

Premarket Approval

- 21 CFR 814
- *Premarket Approval* webpage
- CDRH Learn Modules

What else?

Postmarket?

Premarket Approval

- PMAs → “approved”
  - Reasonable assurance of safety and effectiveness

- 510(k)s → “cleared”
  - Substantial Equivalence

Resources

- *Overview of Device Regulation* webpage: www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation

Resources

- *Class II Special Controls Documents* webpage: www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-documents
- *Premarket Approval* webpage: www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma

Resources

- CDRH Learn Module: *Introduction to the Premarket Approval Application (PMA) Program*: www.fda.gov/cdrhlearn
- CDRH Learn Module: *Premarket Approval Application (PMA) Program: Postapproval Requirements*: www.fda.gov/cdrhlearn

Steps to Bring a New Device to Market

Timing

Steps

1. Classify Your Device and Understand Applicable Regulatory Controls
2. Select and Prepare the Correct Premarket Submission
3. Send your Premarket Submission to the FDA
4. Comply with Applicable Regulatory Controls Including Establishment Registration and Device Listing

1

Classify & Applicable Controls

- Classify your device → know which controls apply
- General controls?
  - 510(k) exempt?
  - Good manufacturing practices (GMP) exempt?
  - Unique Device Identification (UDI)?
- Special controls?
- Premarket approval?

2

Prepare Premarket Submission

- Submission types: IDE, 510(k), PMA, HDE, De Novo
  - Each has its own processes, evidence burden
- Breakthrough? Safer Technologies Program?
- Standards & Conformity Assessment / ASCA
- Good Laboratory Practices
- Small Business Qualification

(IDE: Investigational Device Exemption; HDE: Humanitarian Device Exemption; ASCA: Accreditation Scheme for Conformity Assessment)

3

Submit Premarket Submission

- Prepare eCopy
- Pay MDUFA User Fee (if required)
- Mail submission to FDA

4

Comply

- Comply with all applicable requirements
  - Premarket requirements
    - Registration and Listing → within 30 days of marketing
  - Postmarket requirements

Resources

- www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device

Knowledge Check

Once my 510(k) is approved, I can market my Class II device!

A. True

B. False

C. It Depends

Additional Resources

1. Device Advice

- www.fda.gov/DeviceAdvice
- Written content
- Over 300 pages of total product life cycle regulatory information
- Over 30 regulatory categories

2. CDRH Learn

- www.fda.gov/Training/CDRHLearn
- Multi-media video training modules
- Presentations, computer-based training, webinars
- Approximately 200 modules (most ~ 20 min)
- Mobile-friendly

3. Division of Industry and Consumer Education

Phone: (800) 638-2041

- Hours of operation: 9 am-12:30 pm; 1-4:30 pm

Email: dice@fda.hhs.gov

- DICE will respond within 2 business days

DICE: www.fda.gov/DICE

Summary

- Medical device definition
- FDA's role in regulating medical devices
- Steps to bring a new product to market
- Available resources

Questions


FDA
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