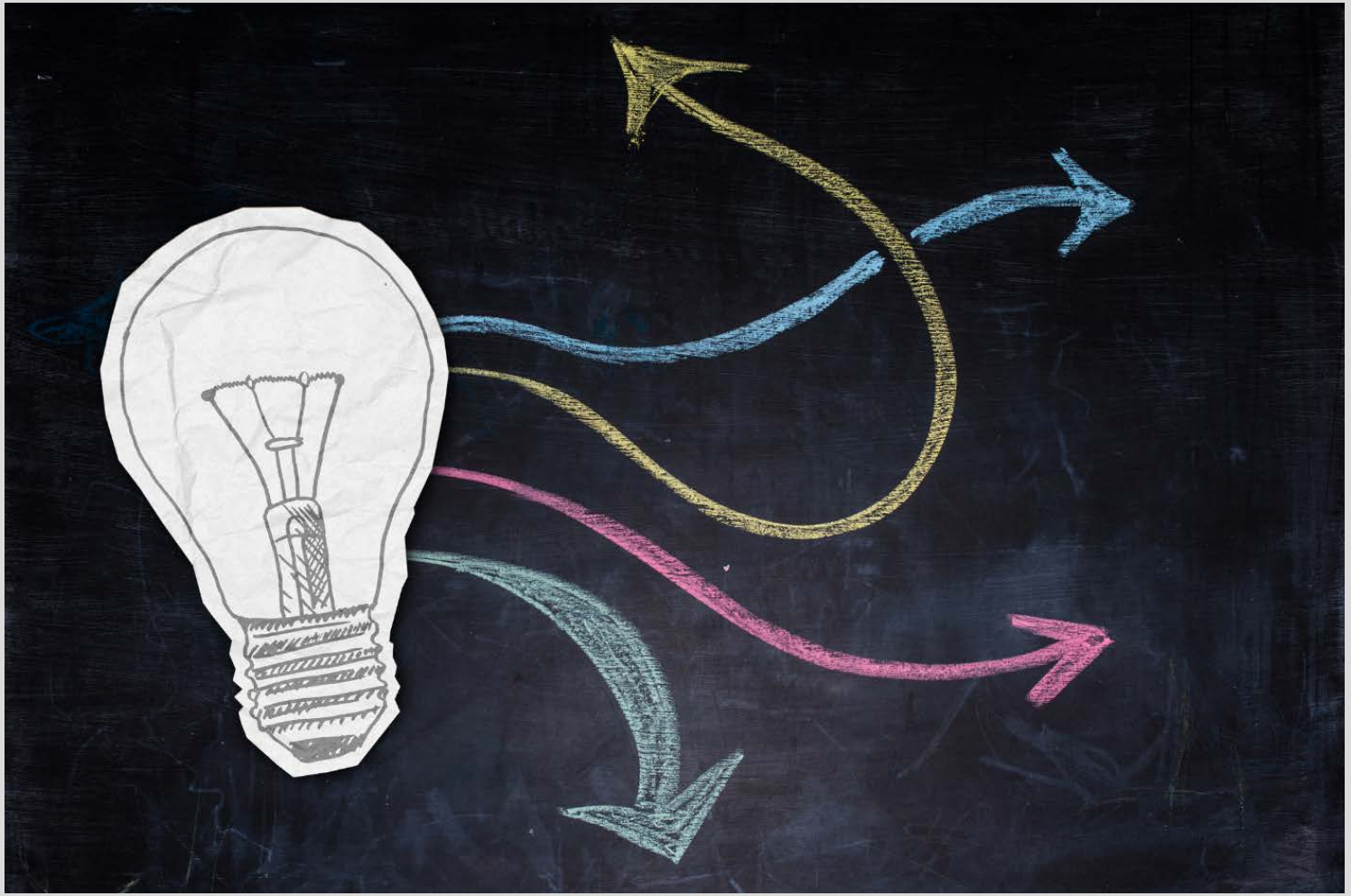
An Introduction to FDA's Regulation of Medical Devices

Elias Mallis
Director
Division of Industry and Consumer Education
Office of Communication Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration



Learning Objectives

- Explain FDA's role in regulating medical devices
- Define a medical device and review basics about device classification
- Describe five steps to get a new product to market
- Identify different types of premarket submissions
- Identify three actions after watching this module

FDA Regulation of Medical Devices

FDA's Role

- Oldest comprehensive consumer protection government agency
- Promote and protect health
- Covers foods, drugs, biologics, cosmetics, animal and veterinary medicine, and tobacco
- CDRH regulates medical devices and radiation-emitting products

CDRH's Role

- Evaluate safety and effectiveness of medical devices
  - Before and after reaching market
- Patients and providers have timely, continued access

FDA Device Regulatory Authority: Laws

- 1976: Medical Device Amendments to Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Subsequent Laws
- 2002 - present: User Fee Programs

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ucm618375.htm

Is My Product a Medical Device?

Medical Device, defined

- Instrument, apparatus, machine, implant, in vitro reagent, including component, part, or accessory
- Diagnoses, cures, mitigates, treats, or prevents disease or condition
- Affects structure or function of body
- Doesn’t achieve purpose as a drug
- Excludes certain software functions
  - data storage, administrative support, electronic patient records

Section 201(h) of FD&C Act

Combination Products

- Involves at least two regulatory component types:

- Example: Drug-Eluting Cardiovascular Stent
- Regulatory responsibilities from involved component types
- One Center usually takes lead
- Office of Combination Products facilitates jurisdiction

www.fda.gov/CombinationProducts/JurisdictionalInformation/ucm148279.htm

Device Regulations

- **21 Code of Federal Regulations (CFR): Parts 800-1050**
  - 800-861: cross-cutting device requirements
    - Example: 812 - Investigational Device Exemption
  - 862-1050: device-specific requirements
    - Example: 876 - Gastroenterology and Urology Devices

- **21 CFR: Parts 1-99**
  - general medical requirements that also apply to medical devices

Device Guidance Documents

- Non-binding
- Elaborate on applicable laws, regulations
- Types
  - **Draft:** Agency's proposed thinking; public comment period
  - **Final:** Agency's thinking; may incorporate public comment

www.fda.gov/RegulatoryInformation/Guidances/default.htm

Device Classification

- Based on device description and intended use
- Determines extent of regulatory control
- Class I, II, or III
  - increases with degree of risk
- Product Codes: three-letter coding to group similar devices and intended use

Classes of Medical Devices

Class	Risk	Controls	Submission
I	Lowest	General	• Exempt* • 510(k)
II	Moderate	General and Special (if available)	• 510(k)* • Exempt
III	Highest	General and PMA	• PMA

*** More common submission requirement of this Class**

Regulatory Controls

- Requirements that apply to a product area (product code)
- Provide consistent requirements to foster predictably safe and effective medical devices
- With appropriate level of regulatory burden/oversight
- Generally broad, but may be specific

General Controls: Examples

Control	Regulation (21 CFR Part)	Brief Description
Labeling	801	provide information for users
Medical Device Reporting	803	report device-related injuries and deaths
Establishment Registration	807	register business with FDA
Device Listing	807	identify devices
Quality System	820	ensure safe, effective finished devices
Adulteration	FD&C Act 501	provide device not proper for use
Misbranding	FD&C Act 502	provide false or misleading labeling

FD&C Act = Federal Food Drug, and Cosmetic Act

Special Controls

- Specific to Class II devices
- Not common
- Usually for well-established device types
- Found in “(b) *Classification*” of regulation
  - example: 21 CFR 876.5860(b)

Special Controls: Examples

- Design, Characteristics or Specifications
- Testing
- Special Labeling
- Guidance Documents

Steps to Get a New Product to Market

1. Establish the Product

✓ **Identify product (device) description**

✓ **Identify purpose**

- intended use (usually broad)
- indications for use (more specific)
- duration of use
- target patient population (age range; disease)

2. Verify that Product is Medical Device

3. Identify Classification and Regulatory Pathway

- Identify regulatory classification
- Classification will generally indicate regulatory pathway (premarket submission type) required for device

4. Develop Valid Scientific Evidence

21 CFR 860.7(c)(1)

- requires valid scientific evidence for safety and effectiveness

21 CFR 860.7(c)(2)

- provides definition of valid scientific evidence

5. Prepare Premarket Submission

Each type has own sets of:

- processes
- applicable laws and regulations
- review times
- evidence burden

Types of Premarket Submissions

Premarket Submission Types

- Investigational Device Exemption (IDE)
- Premarket Notification (510(k))
- Premarket Approval Application (PMA)
- De Novo
- Humanitarian Device Exemption (HDE)

Investigational Device Exemption (IDE)

- Clinical research on investigational devices
- Collect safety and effectiveness data for future marketing application
- Requires approval by Institutional Review Board
- Protect human patients

Premarket Notification - 510(k)

Market application for **low** and **moderate risk** devices

"**Substantial Equivalence**" between new device and a legally marketed device

Compare

- intended use
- device features
- performance testing

Premarket Approval Application (PMA)

- Market application for **highest** risk devices
- Reasonable assurance:
  - safety and effectiveness
- Evidence stands on own
  - not equivalence

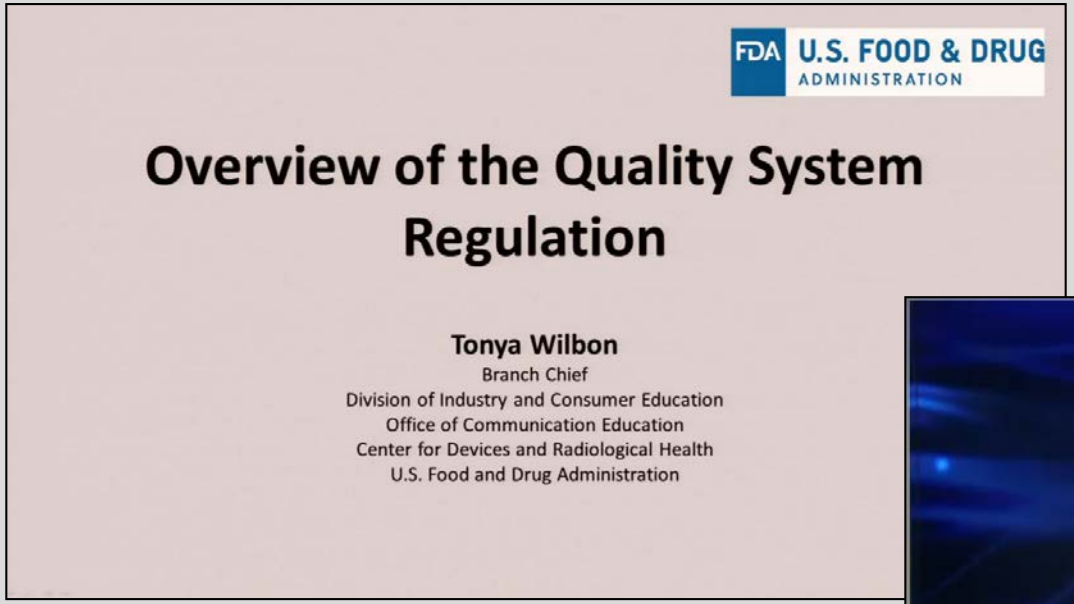
De Novo

- Device has no existing classification regulation
- Marketing process for **novel** devices
- Creates new classification regulation
- Alternative to PMA
- Reduced regulatory burden/controls based on risk-benefit profile of device

Humanitarian Device Exemption
HDE

- Premarket submission for Humanitarian Use Devices
- 8000 individuals per year in United States
- Exempt from effectiveness
- Reasonable assurance of safety and probable benefit

A Note about Quality Systems



CDRH Learn: Overview of the Quality System Regulation (Postmarket Activities)
fda.yorkcast.com/webcast/Play/4abbbeeb0f76423998cab8c782c3e4181d

What Should You Do Next: Resources for You

1. Device Advice

- Written content
- Hundreds of pages of total product life cycle regulatory information
- Over 30 regulatory categories
- “How to” guides

www.fda.gov/DeviceAdvice

2. CDRH Learn

- Multi-media video training modules
- Presentations, computer-based training, webinars
- Over 100 modules
- Most are less than 20 minutes
- Mobile-friendly

www.fda.gov/Training/CDRHLearn

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

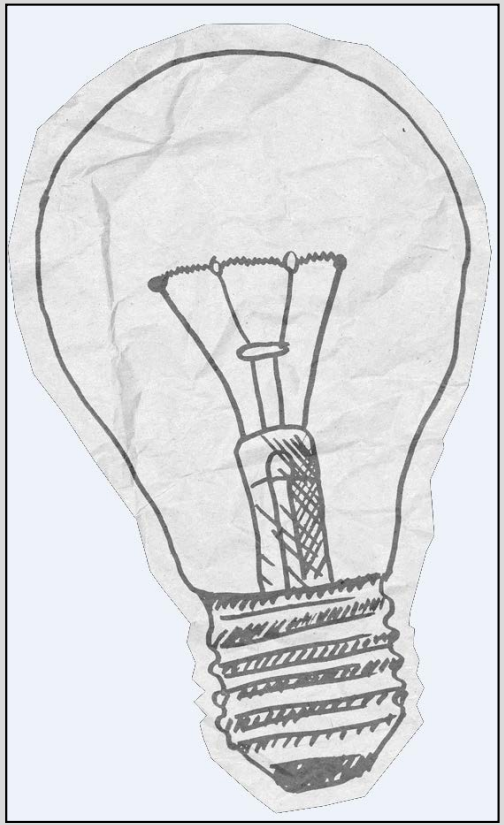
www.fda.gov/DICE

Summary

- FDA regulates medical devices by evaluating safety and effectiveness
- FDA classifies device types with class, regulatory control, and submission requirements
- General process gets new products to market
- FDA has different types of premarket submissions
- FDA develops resources to help you

Your Call to Action

1. Understand your regulatory responsibilities
2. Stay informed
3. Use FDA resources




FDA
U.S. FOOD & DRUG
ADMINISTRATION