U.S. FOOD & DRUG ADMINISTRATION

Overview of Regulatory Requirements: Medical Devices

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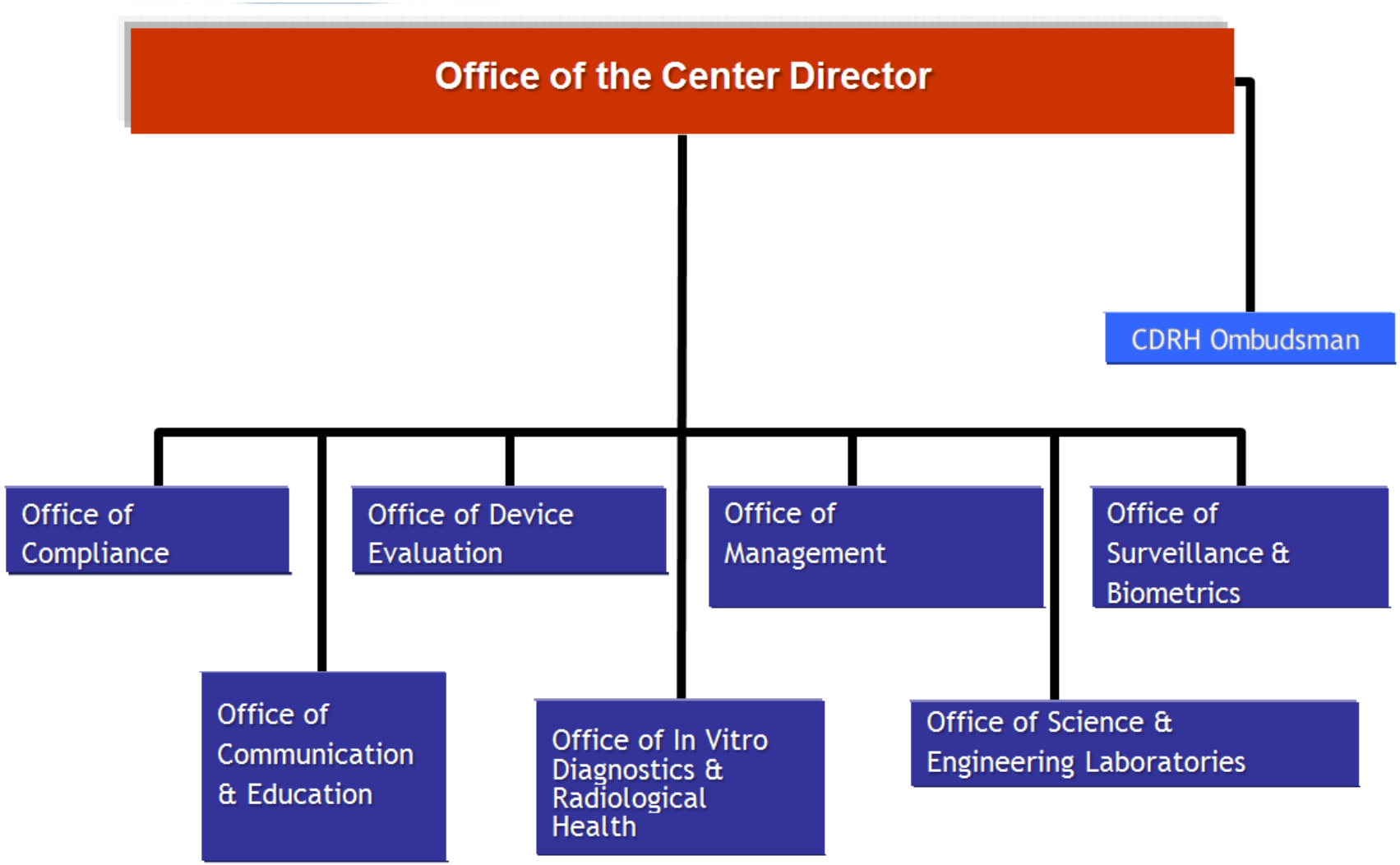
PERU Workshop on Medical Device Regulation and Standards: Policy and Technical Aspects

January 24, 2017

Center for Devices & Radiological Health



Who We Are…

- **CDRH is a team of dedicated, highly skilled, and internationally respected public health employees**
  - Biologists
  - Chemists
  - Physicists
  - Engineers
  - Statisticians
  - Epidemiologists
  - Physicians
  - Microbiologists
  - Nurses
  - Pharmacologists
  - Veterinarians
  - Toxicologists
  - Specialists in Public Health Education & Communication

CDRH Mission

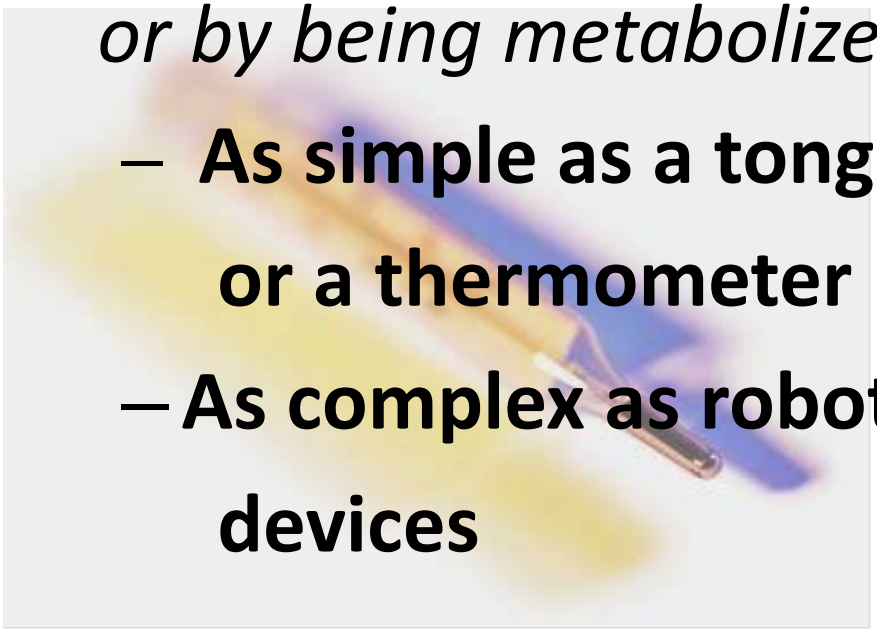
Get safe and effective medical devices to market as quickly as possible…

… while ensuring that medical devices currently on the market remain safe and effective.

Help the public get science-based accurate information about medical devices and radiological products needed to improve health.

A medical device is…

- *The **Section 201(h)** of the Food, Drug and Cosmetic Act defines a medical device as any healthcare product that does not achieve its principal intended purposes by chemical action or by being metabolized.*
  - **As simple as a tongue depressor or a thermometer**
  - **As complex as robotic surgery devices**



The products we regulate…

FDA's Authority: Federal Food Drug and Cosmetic Act (FD&C Act)

- **Medical Device Amendments**
  - May 28, 1976
- **Regulations implementing FD&C Act**
  - Title 21 Code of Federal Regulations (21CFR) Parts 800 - 1299

Device Classification

- **Classification determines extent of regulatory control (Risk Based)**
- **1700 generic groups of devices**
- **Classified within 16 medical specialties**
  - 21 CFR 862-892

862 = Chemistry/Toxicology
864 = Hematology/Pathology
866 = Immunology/Microbiology
868 = Anesthesiology
870 = Cardiovascular
872 = Dental
874 = Ear, Nose and Throat
876 = Gastro/Urology
878 = General Plastic Surgery
880 = General Hospital
882 = Neurological
884 = Obstetrical/Gynecological
886 = Ophthalmic
888 = Orthopedic
890 = Physical Medicine
892 = Radiology

Regulations and Product Codes

- **Regulation Number:** 880.5780

  (a) Medical support stocking to ***prevent the pooling of blood in the legs***. Class II and requires 510(k). **Product code** DWL.

  (b) Medical support stocking for ***general medical purposes***. Class I and is exempt from 510(k). **Product code** FLL.

Classification System
Risk Categorization

- **Class I** ≈780 Low Risk
  - *General Controls*
- **Class II** ≈800 Medium Risk
  - *General Controls and*
  - *Special Controls*
- **Class III** ≈120 High Risk
  - *General Controls*
  - *Premarket Approval*

General Controls

- Adulteration / Misbranding
- Electronic Establishment Registration
- Electronic Device Listing
- Premarket Notification [510(k)]
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)

Special Controls

- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Recommendations or Other Actions
- Special Labeling (e.g., 882.5970, Cranial Orthosis)
- Guidance Documents

Establishment Registration & Medical Device Listing

- **Electronic Registration of Medical Device Establishment**
- **Notification of U.S. Agent for "Foreign Establishments**
- **Electronic Medical Device Listing**
- **Oct. – Dec., Annual Registration**

Premarket Notification 510(k)

- **Marketing Clearance Process**
- **No form - Application submitted at least 90 days before marketing.**
- **Demonstration of Substantial Equivalence (SE) to legally marketed device in U.S.**
- **SE means "Substantial Equivalence" or "*Just as Safe and Just as Effective*".**

When is a 510(k) Required?

- **Marketing for First Time, or**

- **Significant Change to Existing Device that can affect safety and effectiveness (S&E).**

Devices Exempt from 510(k)

- **≈800 devices or 47% of Total Classified Devices are exempt from 510(k).**
  - **Class I 93% or ≈730 devices**
  - **Class II 9% or ≈70 devices**

510(k) Programs

- **Third Party Program** (Accredited Persons)
- **Special 510(k)** - use of Design Controls to assure SE for device modifications
- **Abbreviated 510(k)** - Conformance with Recognized Standards to reduce data

Premarket Approval (PMA)

- Only applies to Class III devices
- Classification requires PMA
- Device found Not “SE” or “NSE”
- “New” - no basis for “SE”
- Proof of reasonable assurance of safety and effectiveness

Investigational Device Exemption(IDE) "Clinical Trials"

- **Unapproved Devices**
  - **Significant risk (SR)**
  - **Non-significant risk (NSR)**
- **Used on human subjects to collect safety and effectiveness data**
- **Protection of human subjects**

Medical Device Labeling

- **Any label or written material on the device or material that accompanies the device**
- **Labeling must provide adequate directions for use unless exempt**
- **Labeling must not be false or misleading**

Quality System (QS) Regulation

- **Quality Assurance System covering the *design and manufacture of medical devices sold in the U.S.***
- **Similar to ISO 13485**
- **Standard for audit of device establishment**

Medical Device Reporting (MDR) "Adverse Event Reporting"

- **Mechanism for FDA to identify and monitor adverse events involving medical devices**
- **Events: Death, Serious Injury and Malfunction**
- **Reported by: Manufacturer, User Facility, and Importers of medical devices**

Postmarket Studies

- **Post-approval Studies** for Class III PMA devices
- **Section 522 Postmarket Surveillance Studies** for Class II and Class III devices

Medical Device Tracking

- **Class II and III devices that:**
  - **Failure would reasonably have serious adverse health consequences;**
  - **Implanted in human body for more that one year; and**
  - **Life sustaining or Life supporting used outside a device user facility**
- **e.g. Replacement Heart Valve (mechanical) and Continuous ventilator**

Code of Federal Regulations (CFR) Citations

- **21 CFR Parts 50, 56, 812:** Clinical Studies
- **21 CFR Part 807**
  - Establishment Registration and Listing
  - Premarket Notification [510(k)]
- **21 CFR Part 814:** Premarket Approval (PMA)
- **21 CFR Part 812:** Investigational Device Exemptions
- **21 CFR Parts 801, 809, 812, 820**
  - Medical Device Labeling
- **21 CFR Part 820:** Quality System Regulation
- **21 CFR Part 821:** Tracking Requirements
- **21 CFR Part 803:** Medical Device Reporting

For Assistance:

- **Division of Industry and Consumer Education (DICE)**
- **Email:** DICE@fda.hhs.gov
- **Phone:** 1(800) 638-2041 or (301) 796-7100
  - *Press 1 to speak to the Consumer Team*
  - *Press 2 to speak to the Industry Team*
- **Hours of Operation**:
  9:00 am – 12:30 pm Eastern Time
  1:00 pm – 4:30 pm Eastern Time