Overview of Regulatory Requirements: Medical Devices

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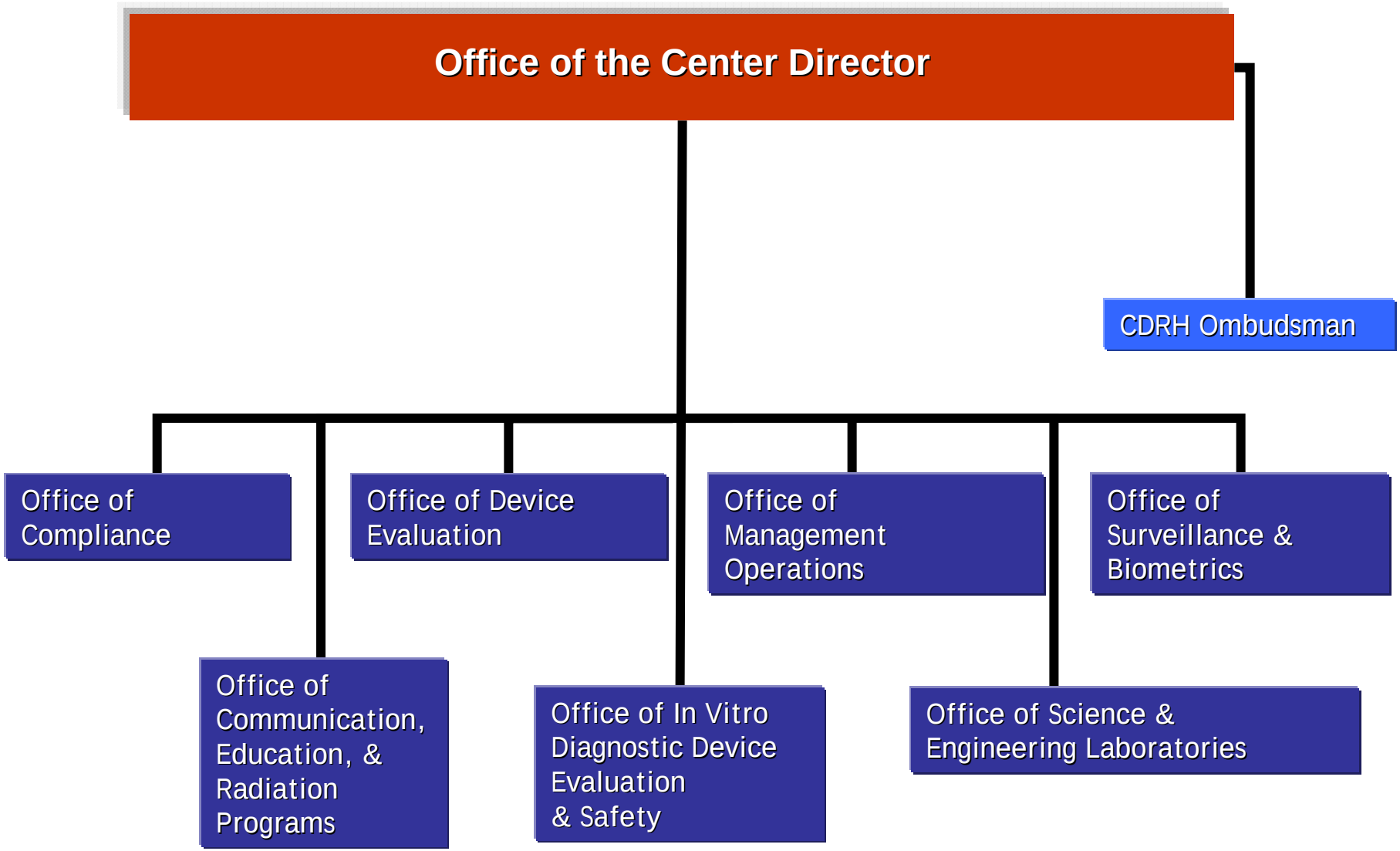
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Who We Are…

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

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

510(k) Device User Fees

- **Standard Fee**
- **Small Business Fee**
  - ***(≤$100 million in gross receipts or sales)***

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

PMA Device User Fees

- **Standard Fee**
- **Small Business Fee for First application**
  - ***≤$30 million*** ***Fee is Waived***
  - ***≤$100 million***

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

Division of Small Manufacturers, International and Consumer Assistance (DSMICA)

Telephone/Fax/Email

- Email: **dsmica@fda.hhs.gov**

- Toll-Free Number
  - **Phone: 800-638-2041 or 301-796-7100**
  - **Fax: 301-847-8149**

- Medical Device Specialists
  - **Monday - Friday 8:00 a.m. to 5:00 p.m. EST**

Thank You for Watching!

www.fda.gov/CDRH