Overview of Regulatory Requirements: Medical Devices

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Center for Devices and Radiological Health
Food and Drug Administration
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
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

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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
  \[\approx 780\] Low Risk

• Class II
  – General Controls and Special Controls
  \[\approx 800\] Medium Risk

• Class III
  – General Controls
  – Premarket Approval
  \[\approx 120\] 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**
  - \((\leq \$100 \text{ million in gross receipts or sales})\)
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 than 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
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