Overview of Medical Device Regulations

FDA Small Business
Regulatory Education for Industry (REdI)
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CDRH Mission, Vision and Shared Values

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm300639.htm

• Protect and Promote public health

• Timely access to Safe, Effective, and High-Quality medical devices and safe radiation-emitting products

• Provide consumers, patients, caregivers, and providers with understandable and accessible science-based information

• Facilitate medical device Innovation
Legislative Mandates

1968  Radiation Control for Health & Safety Act (RCHSA)
1976  Medical Device Amendment of 1976
1988  Clinical Laboratory Improvement Amendments (CLIA)
1990  Safe Medical Devices Act (SMDA)
1992  Mammography Quality Standards Act (MQSA)
1992  Medical Device Amendments
1997  Food & Drug Administration Modernization Act (FDAMA)
2002  Medical Device User Fee and Modernization Act (MDUFMA)
2005  Medical Device User Fee Stabilization Act (MDUFSA)
2007  Food and Drug Administration Amendments Act of 2007 (FDAAA)
2012  FDA Safety and Innovation Act (FDASIA)
Who We Are…

• CDRH is a team of over 1,500 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 and Communication
CDRH Mission

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

Benefits  Risks

... 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.

March 28, 2012 Final Guidance for Industry and FDA Staff - Factors to Consider when Making Benefit-Risk Determinations in Medical Device Reviews
A medical device defined

“… an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

Section 201, Food Drug and Cosmetic Act
A medical device defined

• intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, or

• intended to affect the structure or any function of the body of man,

• and which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes.” (in other words, not a drug)
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

• 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
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
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
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

• Annual Registration Fee (no waivers)
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, e.g. Rx Devices
• 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
Submission Types

• Premarket Notification [510(k)]
• Premarket Approval (PMA)
• Investigational Device Exemption (IDE)
• Humanitarian Device Exemption (HDE)
• De Novo
Premarket Notification 510(k)

- Marketing Clearance Process

- No 510(k) 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

• Change to Existing Device that could Significantly Impact S&E
  – January 10, 1997 – “Deciding When to Submit a 510(k) for a Change to an Existing Device”
510(k) Programs

- **Special 510(k)** - use of Design Controls to assure SE for device modifications

- **Abbreviated 510(k)** – Leverage Established Information (e.g. performance test method, guidance documents, device-specific standards) to Reduce Documentation in 510(k) submission.

  - Third Party Program (Accredited Persons)
Premarket Approval (PMA)

- Only applies to Class III “High Risk” devices
- Classification regulation requires PMA
- Device found Not “SE” or “NSE”
- No eligible predicate device, i.e. no basis for “SE” finding
- Independent assessment of reasonable assurance of safety and effectiveness
Investigational Device Exemption (IDE) “Clinical Trials”

• Unapproved Devices or Approved Devices for a New Indication

• Used on human subjects to collect safety and effectiveness data

• Protection of human subjects
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

• Approximately 17 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. Implantable pacemaker pulse generator and Continuous ventilator.
Code of Federal Regulations (CFR) Citations

- 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

CFR Online at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
Contact DSMICA

• Email: dsmica@fda.hhs.gov

• Phone Number
  800-638-2041 or 301-796-7100,
  Monday - Friday 8:00 a.m. to 5:00 p.m. EST

*Education fosters voluntary compliance and self-reliance!*
Questions?

www.fda.gov/Medical Devices