

The Regulation of Medical Devices

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Outline

- Statutory Acts
- Definition of a Device
- Device Classification
- Section 510(k) & Purpose
- Premarket Approval (PMA)
- Investigational Device Exemption (IDE)
- Humanitarian Device Exemption (HDE)
- Safe Medical Devices Act of 1990
- FDA Modernization Act (FDAMA) 1997
- Medical Device User Fees 2002 & 2007

Statutory Acts

<http://www.fda.gov/cdrh/lawsregs.html>

- Pre 1976 – Devices regulated under drug authorities
- May 28, 1976 - Medical Device Amendments (PL 94-295)
- Safe Medical Devices Act (SMDA) of 1990
- FDA Modernization Act (FDAMA) of 1997
- Medical Device User Fees Acts of 2002 & 2007

Definition of a Device (201(h))

- an instrument, apparatus, implement, machine, contrivance implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is -
 - (1) recognized in the official National Formulary, or the US Pharmacopeia, or any supplement to them

Definition of a Device (cont)

- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals, and

Definition of a Device (cont)

- which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

(201(h))

Device Classification

- Device Classes
 - Class I - General Controls - 43%
 - 91% Exempt from 510(k)
 - Class II - Special Controls - 51%
 - 7% Exempt from 510(k)
 - Class III - Premarket Approval - 6%
- 1870+ Device Categories
- 18 Classification/Advisory Panels
- Transitional Devices

General Controls

- Adulteration and Misbranding (501&502)
- Registration, Listing, & 510(k) (510)
- Banned Device (516)
- Notification and other Remedies (518)
- Records & Reports (519)
- Quality Systems Regulation (520)

Special Controls

- Standards
- Post-market Surveillance
- Patient Registries
- Guidelines
- Recommendations
- Other as Necessary

Section 510(k) of the Act

- Established 90 day timeframe
- Format by Regulation
- Device Class
- Action to comply with Section 514 and 515
- Implementation of Section 510(k)
 - 21 CFR Section 807 Subpart E

Purpose of 510(k)

- Demonstrate “substantial equivalency”
- Clearance to market

510(k) Review Guidance

<http://www.fda.gov/cdrh/devadvice/314.html>

- Blue Book Memo - K-86-3
 - <http://www.fda.gov/cdrh/k863.html>
- 510(k) Decision Tree
- Device Specific Guidance
 - <http://www.fda.gov/cdrh/guidance.html>
- Format for 510(k) Guidance
 - <http://www.fda.gov/cdrh/ode/guidance/1567.pdf>

Devices Which Need a PMA

- “New Devices”
 - Premarket Notification
 - Not Substantially Equivalent
 - Post Amendments Devices
- Transitional Class III Devices
 - Previously Regulated as New Drugs

Transitional Devices

- Some were classified:
 - Gauze
 - Adhesive Tape
 - Tampons
 - Dialysis Fluid
 - Denture Cushions

Transitional Devices (Cont'd)

- Others remain in Class III
 - Injectable Silicone
 - Adsorbable Sutures (some reclassified into class II)
 - Adsorbable Dusting Powders
 - Injectable Teflon
 - Soft Contact Lenses (reclassified into Class II)

Devices Which Need or Will Eventually Need a PMA

- Pre-Amendments Class III Devices
- SE Post-Amendment Class III Devices
- < 25 device types remaining

Premarket Approval

<http://www.fda.gov/cdrh/devadvice/pma/>

- Class III Devices are Subject to Premarket Approval
 - Reasonable Assurance Safety and Effectiveness
 - Valid Scientific Evidence
 - Risk/Benefit
- vs
- Substantial Equivalence

Safety and Effectiveness

- Considerations
 - Persons for whose use the device is intended
 - Conditions of use of the device
 - Possible benefit to health vs probable injury or illness from use
- Reliance on Valid Scientific Evidence Only

Investigational Device Exemption

<http://www.fda.gov/cdrh/devadvice/ide/index.shtml>

- Intent to study:
 - New intended use of approved device; or
 - New device
- Physician may be Investigator & Sponsor
- FDA approval of an IDE application required?
 - Significant Risk (SR) study -- yes
 - Non-significant Risk (NSR) study -- no

Significant Risk?

Presents a potential for serious risk to the health, safety, or welfare of the subject and may be:

- An implant;
- Life supporting/life sustaining;
- Of substantial importance in diagnosing, curing, mitigating, or treating disease; or,
- Otherwise presents potential for serious risk.

Significant Risk -- Who Decides?

<http://www.fda.gov/cdrh/d861.html>

- Sponsor (Sponsor/Investigator (S/I) or firm) presents their determination to IRB
 - IRB agrees, consults, or defers
 - FDA - ultimate authority
- ⇒ If uncertain, use SR/NSR Guidance and/or consult with IDE Staff

Non-Significant Risk vs Significant Risk

NSR

- IRB approval
- Informed Consent
- Examples (later)

SR

- IRB approval
- Informed Consent
- *FDA approval*
- 30 Day Review/Letter always sent
- CMS Reimbursement Code
- Examples (later)

Non-Significant Risk Devices

<http://www.fda.gov/cdrh/d861.html>

- Daily wear contact lenses
- Conventional endoscopes
- Dental filling material
- General biliary & vascular catheters
- TENS devices for pain
- Most wound dressings

Significant Risk Devices

<http://www.fda.gov/cdrh/d861.html>

- Vascular & therapeutic catheters
- Anesthesia machines
- Epidural & spinal catheters
- Dialyzers
- Implants
- Contraceptive devices
- Extended wear contact lenses

Humanitarian Device Exemptions (HDEs)

<http://www.fda.gov/cdrh/devadvice/hde.html>

- For diseases/conditions affecting less than 4,000 patients in US per year
- No approved alternative device
- Exemption from effectiveness requirement of the Act
- Is a marketing approval
- 75-day review clock

HDE Examples

- Implantable Replacement Heart
- Right Ventricular Assist System
- Ventricular Septal Defect Occlusion System
- Bladder Stimulator for Urination on Demand
- Finger Prosthesis for Patients with Painful Osteo-Arthritis
- Fetal Bladder Stent
- Urological Stimulator for Children with Neurogenic Bladder due to Spina Bifida
- Vertical Expandable Prosthetic Titanium Rib

“Off-label” Use of Devices

- “Practice of Medicine” Policy states that a physician should:
 - Be well informed about the product
 - Use firm scientific rationale and sound medical evidence
 - Maintain records on use and effects
- IDE not req'd; IRB/IC approval may be

Safe Medical Devices Act of 1990 (SMDA)

- Expanded 1976 authorities
 - Codified FDA practice on 510(k) decision practices
 - <http://www.fda.gov/cdrh/ode/655.pdf>
 - Truthful and Accurate
 - Summary/Statement
 - Class III Summary
 - Required clearance order before marketing

FDA Modernization Act (FDAMA)

- 1997

<http://www.fda.gov/cdrh/modact/modguid.html>

- 3rd Party Review
- Exemptions for Class I & II
- Labeled Intended Use
- Evaluation of Automatic Class III Designation (De Novo)
- Recognize Standards
 - Over 750 recognized as of 9/08
- Least Burdensome (10/4/02 Guidance)

Examples of De Novo Devices

- Air-conduction Hearing Aid
- Swallowable Imaging System
- Heimlich Maneuver Assist Device
- Sulfide Detector for Periodontal Disease
- Laser for Fluorescence Caries Detection
- Several In Vitro Diagnostic Devices
 - West Nile Virus antibody ELISA
 - Influenza Nucleic Acid Assay
 - Malaria Test

Medical Device User Fee and Modernization Act of 2002 (MDUFMA)

<http://www.fda.gov/cdrh/mdufma/>

- I. User Fees
- II. Performance Goals
- III. Third-Party Inspections
- IV. Reprocessed Single-Use Devices
- V. Additional Provisions

Applications/Submissions Subject to Fees (updated for 2007 law)

- Premarket Application (PMA and PDP)
- Premarket Report
- Panel Track Supplements
- 180-day Supplements
- BLA & Efficacy Supplements
- Real-time Supplements
- 30-day Notice
- PMA Annual Report
- Premarket Notification [510(k)] Submissions
- 513(g) Request for Information
- Device Registration

Exceptions to user fees

- Humanitarian Device Exemption
- Further Manufacturing Use Supplements
- State and federal sponsors (non-commercial)
- 510(k) submissions reviewed by third parties
- PMA or 510(k) Pediatric Only Conditions of Use
- Investigational Device Exemptions (IDEs)

Performance Goals

- General Goal of User Fees
 - To support an improved review process through added resources resulting in more predictable and timely approval/clearance of safe and effective products

Performance Goals (continued)

- General Comments
 - Goals are defined in letter from DHHS Secretary to Congress
 - Based on decision goals
 - Measured in FDA days
 - Separate goals for each submission type

What is the Purpose of Third Party Inspection?

<http://www.fda.gov/cdrh/ap-inspection/index.html>

- FDA will have greater flexibility to use its limited inspectional resources
- Industry will have ability to schedule AP and other conformity assessment body (CAB) inspections simultaneously

Reprocessed Single-Use Devices

- Reprocessed single-use device must be “prominently and conspicuously” labeled:
Reprocessed device for single use. Reprocessed by [name of manufacturer that reprocessed the device]
- New type of premarket submission, the *premarket report*, with additional data requirements that focus on reprocessing for Class III devices
- Validation Data Required

Additional Provisions

- Electronic Labeling
- Modular Review of PMAs
- Pediatric Use
- Combination Products

MDUFA of 2007

- Updating of goals and fees provision of MDUFMA
- Eliminated cycle goals – only decision goals
- Some new provisions

FY 08 Submission Numbers

- 510(k)s received
 - Originals 3,848
- PMA received
 - Originals 31
 - Supplements (all types) 1,552
- IDEs received
 - Original 221
 - Supplements 4,439