Everything You Ever Wanted to Know About Medical Device Marketing Clearance

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Outline

Sources of Information
Statutory Basis
Routes to Market (Clearance Processes)
Investigational Use
Submission Fees
Contacts

- Web site: WWW.FDA.GOV/CDRH
- Division of Small Manufacturers
  Assistance: 1-800-638-2041
- Program Operations Staff; IDE, 510(k), PMA: (301) 594-1190
- Radiology Branch: (301) 594-1212
- For Post-market reporting:
  MedWatch: 1-800-FDA-1088
Useful Pages

- Device Advice
- Guidance Documents
- Voluntary Standards
- Obtain Market Clearance / Approval
Device Advice is CDRH's self-service site for medical device and radiation emitting product information. Device Advice is an interactive system obtaining information concerning medical devices.
Useful Pages

- Device Advice
- Guidance Documents
- Voluntary Standards
- Obtain Market Clearance / Approval
Guidance Documents

Key Topics...
- Annual Guidance Document Agenda

About Guidance
- What is guidance?
- Abbreviations of CDRH offices producing guidance documents

Resources
- Online search of CDRH guidance documents
- Guidance documents from FDA
- CDRH Facts on Demand (FOD)

Updated June 19, 2003
Useful Pages

- Device Advice
- Guidance Documents
- Voluntary Standards
- Obtain Market Clearance / Approval
Standards Program

Recent Items...

- Modification to the List of Recognized Standards

How to use this program

- Recognition and Use of Consensus Standards
- FDA Recognized Consensus Standards Database
- Recommending Standards for CDRH Recognition

Guidance

- Frequently Asked Questions on the Recognition of Consensus Standards
- Recognition and Use of Consensus Standards
- Use of Standards in Substantial Equivalence Determinations
- CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition

Other Resources

- Federal Register documents
- Standards Organizations
- International issues
- International Center Liaison
  Representative Roster (PDF) or (Word)
- National Center Liaison
  Representative Roster (PDF) or (Word)

Updated August 1, 2002
Useful Pages

- Device Advice
- Guidance Documents
- Voluntary Standards
- Obtain Market Clearance / Approval
Getting To Market With A Medical Device

- Introduction
- Three Steps to Obtaining Marketing Clearance from CDRH
- Classify Your Device
- Selecting the Appropriate Marketing Application
- Other Requirements Besides Marketing Clearance
- In Vitro Diagnostic Devices

Introduction

One of the most difficult aspects of getting a medical device to market is KNOWING WHERE TO BEGIN i.e., what are the steps for marketing and in what order they are to be taken. Essentially, medical devices are subject to the general controls of the...
Medical Device Amendments

May 28, 1976
Role of FDA

Establish *reasonable* assurance of the safety and effectiveness of medical devices marketed in the U.S.
Statutory Basis:

Federal Food, Drug, and Cosmetic Act

As amended by:

- Medical Device Amendments-1976
  - Devices Classified

- Safe Medical Device Act (SMDA)-1990
  - Expanded role
  - More detail

- FDA Modernization Act-1997
  - Redefined (more circumscribed) role
  - More interactive with sponsors
  - Expanded/earlier access of new technologies to patients
Statutory Basis:
Federal Food, Drug, and Cosmetic Act (2)

- Medical Device User Fee and Modernization Act (MDUFMA) of 2002
  - User fees
  - Review time goals
Medical Device

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) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, or
2) 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.

Section 201, Food Drug and Cosmetic Act
Medical Device Approval Process

- Most devices on market prior to May 28, 1976 were “grandfathered”
- Marketing clearance for these devices through 510(k) clearance process—Substantially Equivalent
- 510(k)d devices are not approved
- Most radiological products on market using this process
Routes to Market

- Premarket Submission
  - 501(k)

- Premarket Approval Application
  - PMA
Grandfathered Devices

Pre 1976 devices placed into three classes

- Class I- General controls
- Class II- Special controls
- Class III- PMA
Class I

- Low risk devices
- Safety and effectiveness assured by
  - Good Manufacturing Practices
  - Post-marketing surveillance
  - Registration and listing
Class II

- Class I controls plus
- “Special controls”
  - Voluntary standards
  - Mandatory standards
  - Guidance
  - Manufacturing inspection
Class III

- Premarket approval application that establishes Safety and Effectiveness
510(k)

Substantially Equivalent – *New device is compared to a similar device that is on the market.*

Device need be only as good (or bad) as what was on market in 1976

510(k) clearance *does not* assure effectiveness

Many devices are exempt from 510(k) submission

Review time about 90 days
Medical Device Approval Process

- Devices that sustain life, implants, in class III, or can not be shown substantially equivalent are approved by PMA process.

- In a PMA the sponsor must demonstrate that the device is safe and effective for intended use.
PMA’d Devices

Less than 2% of submissions approved via PMA (similar to NDA)

– Magnetic Resonance
– Bone Sonometry
– Diagnostic ultrasound as an aid in determining breast malignancy
– CAD devices
PMA Content

- Indications for use
- Device description
- Laboratory testing
- Preclinical studies
- Clinical studies
- Labeling
- Manufacturing (GMP)
PMA Process

- Multi discipline review
- May be reviewed by FDA advisory panel
- FDA review time = 180 days
- Data is proprietary
Routes to Market

- Premarket Submission
  - 501(k)
  - “Me Too” process

- Premarket Approval Application
  - PMA
  - *Determinaton of Safety and Effectiveness*
Investigational Use

- Safety and effectiveness studies on devices that are not market cleared
- Needs IRB approval
- Needs informed consent
- FDA involvement depends on “significant risk” vs. “non-significant risk”
- If significant risk = FDA IDE approval needed.
- If not significant risk = Only IRB approval needed
Investigational Use

- Investigational studies can be multi-phase
- Studies should be well presented
  - Intended indications for use
  - Literature review
  - Scientific basis
  - Safety issues well understood
  - Protocol scientifically sound
  - Reasonable study endpoints
Pre-investigational Contacts

- FDA/CDRH will meet with you.
- Meetings early in the development/testing stage are desirable
- Meetings are not depended on “significant risk” status
- We work on a “least burdensome” basis
Extensive sources of information are available.

There are multiple pathways to market clearance.

FDA decisions are driven by risk and effectiveness issues.

Contact the appropriate FDA/CDRH component early in the process.
## FY2004 Submission Fees

<table>
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<tr>
<th>PMA</th>
<th>Fee Rates</th>
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<tr>
<td></td>
<td>Full</td>
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<tr>
<td>Full Fees</td>
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<tr>
<td>180-Day Supps</td>
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<tr>
<td>Real-Time Supps.</td>
<td>$ 14,890</td>
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<tr>
<td>510(k)’s</td>
<td>$  3,480</td>
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Fee Exemptions and Waivers

- First time PMA application from a small business – waiver
- Any device intended to be used solely for pediatric use – exempt from fees
- State or Federal government applications – exempt from fees (ex for comm. dist.)
- Small Business = Ann gross revenue ≤ $30M
What the “Critical Path” Is

- A serious attempt to bring attention & focus to the need for more scientific effort and publicly-available information on evaluative tools

- Evaluative tools: The techniques & methodologies needed to evaluate the safety, efficacy & quality of medical devices as they move down the path
Contact

- **Web Address:**
  
  http://www.fda.gov/oc/initiatives/criticalpath/

- **Open Docket:**
  
  http://www.fda.gov/dockets/ecomments
  
  Docket # 2004N-0181

- **CDRH webpage (under news and events)**
  
  provides links to the critical path white paper and docket:
  
  http://www.fda.gov/cdrh/