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HST.939 Designing and Sustaining Technology Innovation for Global Health Practice
Spring 2008

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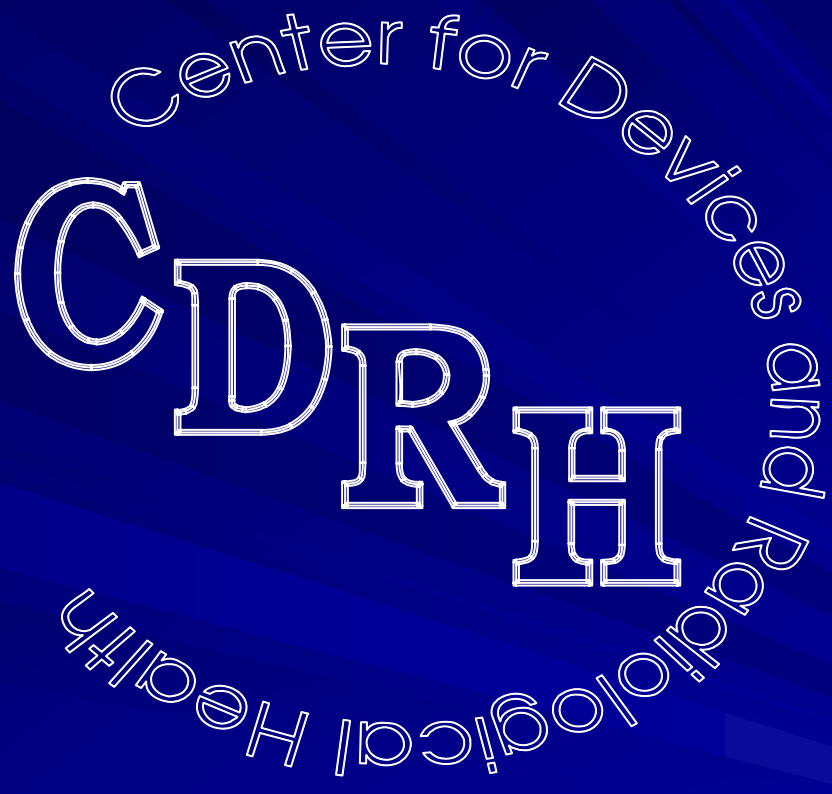
Center for Devices and Radiological Health
CDRH

Everything You Ever Wanted to Know About Medical Device Marketing Clearance

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Chief, Radiological Devices Branch

Office of Device Evaluation

Center for Devices and Radiological Health

FDA

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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

FDA U.S. Food and Drug Administration

Department of Health and Human Services

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C·D·R·H Center for Devices and Radiological Health

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A–Z Index | Send Feedback

Industry Assistance

- Device Advice
- Guidance documents
- Industry Support
- International issues
- Medical device reporting (MDR)
- Obtain market clearance / approval
- Ombudsman
- Standards
- Third party review
- Third party inspection

Health Topics

News & Events

FDA Critical Path Initiative - The Critical Path to New Medical Products
More Information

Possible Barriers to the Availability of Medical Devices Intended to Treat or Diagnose Diseases and Conditions that Affect Children;
Request for Comments

Announcement of 2nd Annual MDUFMA Stakeholder Meeting
Thursday, November 18, 2004
More Information

FDA Breast Implant Consumer Handbook - 2004 Edition
More Information

FDA Patient Safety News - June Edition
More Information

View All Recent Items

SUBSCRIBE to Daily Updates

Device Program Areas

Key topics

- Heart Health Online
- Diabetes
- LASIK
- CT scanning
- Breast implants
- Cell phones
- Patient Safety Portal
- Internet sales

Featured Site

Consumer Information on Wireless Phones

Useful Pages

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


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Overview of Regulations
Is Your Product Regulated?
Classify Your Device
How to Market Your Device
Does Your Product Emit Radiation?
Registering Your Establishment
Listing Your Device
Premarket Notification 510(k)
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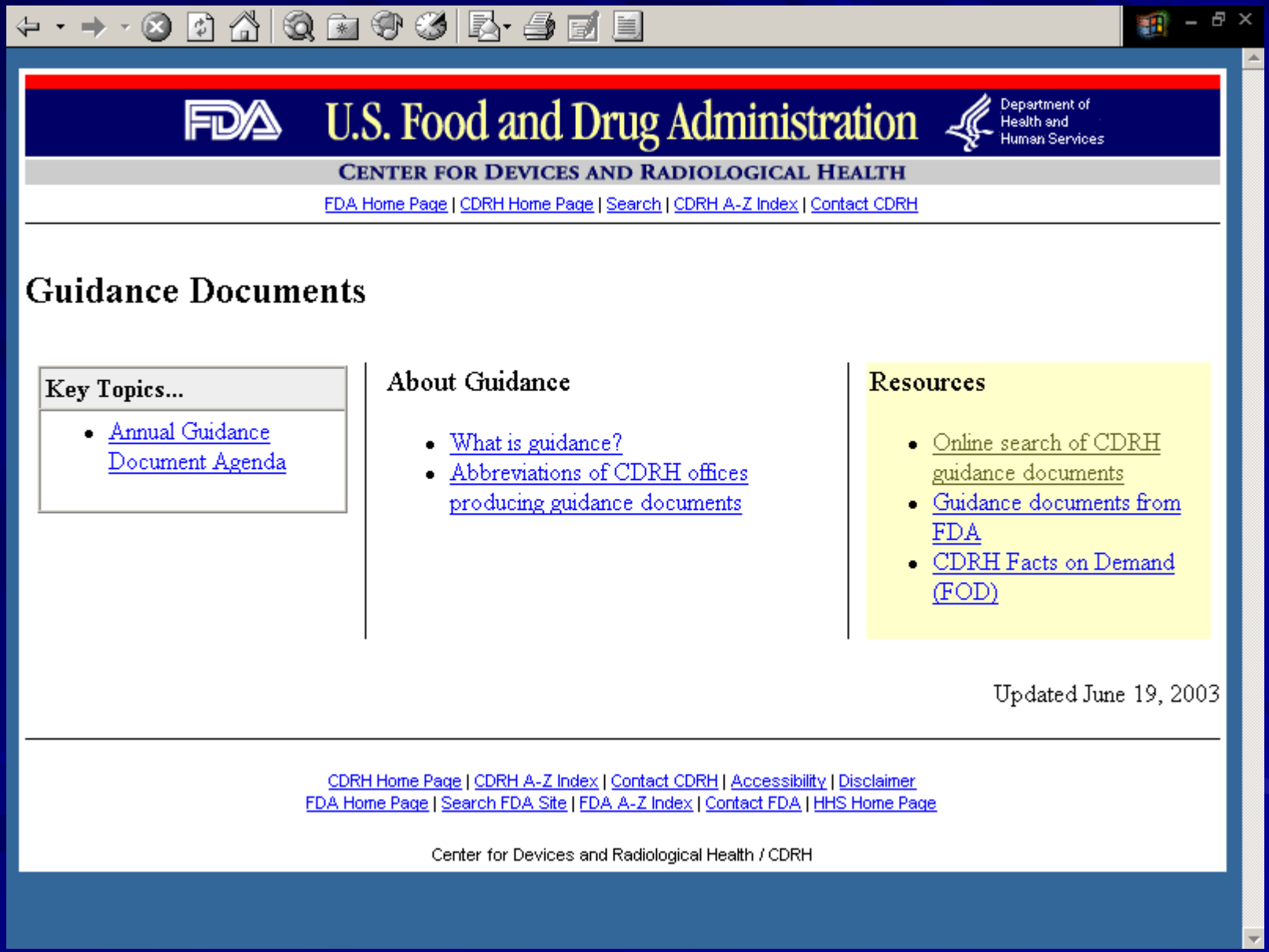
Useful Pages

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



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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

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Useful Pages

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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


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Please note: as of October 1, 2002, FDA charges fees for review of Premarket Notification 510(k)s and Premarket Approvals
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*
  - ***Determination 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

Summary

- 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

	Fee Rates	
PMA	Full	Sm. Bus.
Full Fees	$206,811	$78,588
180-Day Supps	$ 44,464	$16,896
Real-Time Supps.	$ 14,890	$5,658
510(k)’s	$ 3,480	$2,784

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/