



510(k) Third Party Reviews

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Director

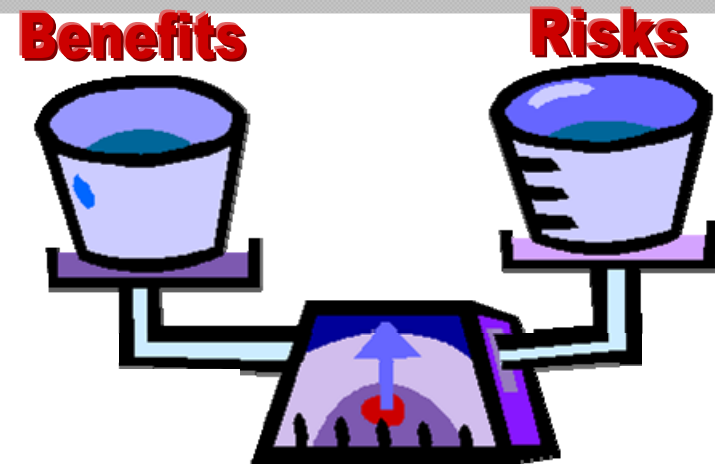
Center for Devices and Radiological Health (CDRH)

U.S. Food and Drug Administration



CDRH's Mission

- Get **safe and effective** devices to market as quickly as possible.
- Ensure that 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 Food, Drugs and Cosmetics 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 robotic surgery devices**



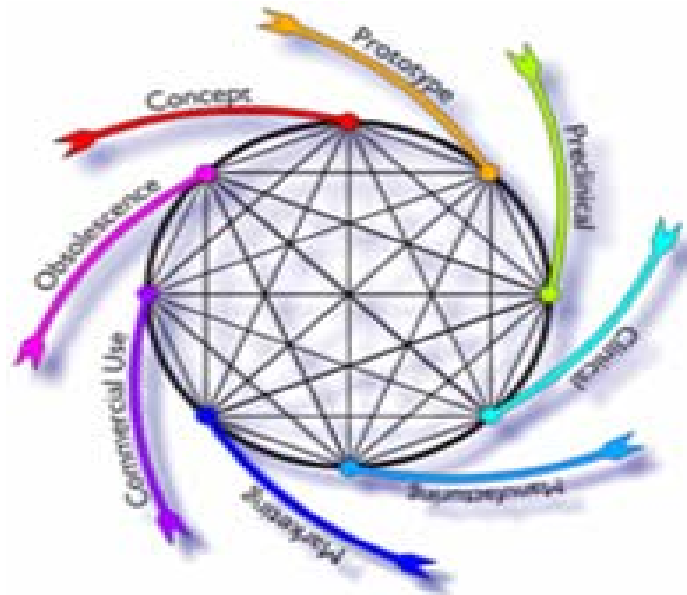
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“Total Product Life Cycle” Vision

Encouraging
Product
Development

Ensuring
Postmarket
Safety



Access to
Innovation



FDA's Approach to Medical Device Regulation

- 1. Base degree of control on risk**
- 2. Weigh benefit vs. risk to determine safety and effectiveness**
- 3. Use valid scientific evidence**
- 4. Consider least burdensome means**
- 5. Provide "reasonable assurance"**



Safety & Effectiveness

Key Elements

■ **Valid scientific evidence**

- Looking at clinical outcomes is within our regulatory mandate
- On the other hand, we do not regulate practice of medicine

■ **Well defined intended use**

■ **Adequate labeling**



Risk-Based Paradigm

**The law gives us the flexibility to
calibrate our regulatory touch to
the level of potential risk posed
by new products**



Device Classification

Medical Device Classes:



Class I

General Controls
Most exempt from premarket submission



Class II

Special Controls
Premarket Notification
[510(k)]



Class III

Premarket
Approval

Require Premarket Application [PMA]

Additional Classification:



"De Novo"

Device "types" that have never been marketed in the U.S., but whose safety profile and technology are now reasonably well understood



Humanitarian Device Exemption (HDE)

Devices for orphan diseases

Intended to benefit patients in diagnosis and/or treatment of disease or condition affecting or manifested in fewer than 4,000 patients per year in the United States



510(k) – Brief Overview

- **Section 510(k) of FD&C Act requires premarket notification**
- **Used to determine “substantial equivalence”**
- **Main marketing clearance path for medical devices (3,800 per year)**
- **Requires significant FDA resources**



Third Party Review Program *(a.k.a. “510(k) Accredited Persons Program”)*

- Gives 510(k) submitters the option of using accredited, non-Federal organizations to review 510(k)s for low and moderate risk devices, in place of FDA’s review
- Authorized by §523 of the FD&C Act



How the Program Operates

- 510(k) submitter may elect to use accredited Third Party (TP) or FDA for review of eligible device
- If TP route is chosen:

Applicant contracts with TP for review



TP reviews 510(k) & makes recommendation to FDA



FDA issues final decision (30 days)



Statutory Limitation – §523(a)(3)

Third parties may not review:

- **Class III devices**
- **Class II devices that:**
 - Are permanently implantable
 - Are life sustaining/supporting, or
 - Require clinical data in 510(k)s
- **Devices that require input from other Centers (e.g., combination devices)**



Accreditation of Third Parties

- **FDA serves as accreditation body**

- **Emphasis is on adequacy of:**
 - Personnel and procedures to ensure competent reviews
 - Controls to prevent conflict of interest

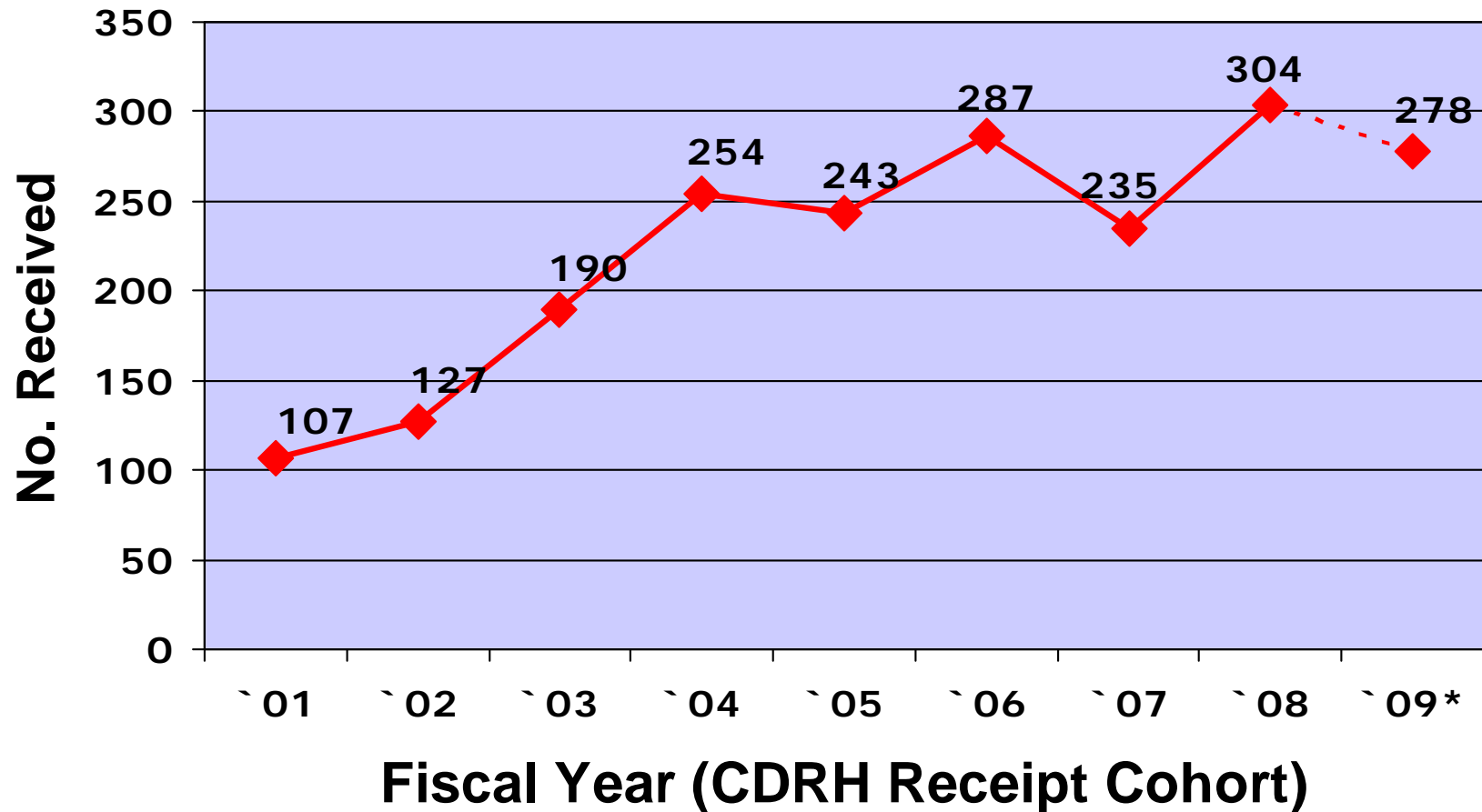


Organizations Accredited by FDA to Conduct Select 510(k) Reviews

- **British Standards Institution (United Kingdom)**
- **Center for Measurement Standards, ITRI (Taiwan)**
- **Cheiroon, BV (Netherlands)**
- **CITECH**
- **Intertek Testing Services**
- **KEMA Quality, BV (Netherlands)**
- **NIOM Scand. Inst. of Dental Materials (Norway)**
- **Regulatory Technology Services, LLC**
- **TUV SUD America, Inc.**
- **TUV Rheinland of North America, Inc.**
- **Underwriters Laboratories, Inc.**



510(k)s With A Third Party Review Under §523



*Straight-line projection based on actual data through 26-Jan-2009



How Often Does FDA Agree with the Third Party Recommendation?

- CY 2008 Decision Cohort -	
Outcome	Percent of 510(k)s*
Accepted 1st cycle	51%
Accepted 2nd cycle	29%
Accepted 3rd cycle or beyond	11%
Ultimately not accepted	8%

*Based on 311 510(k)s; column does not add to 100% due to rounding

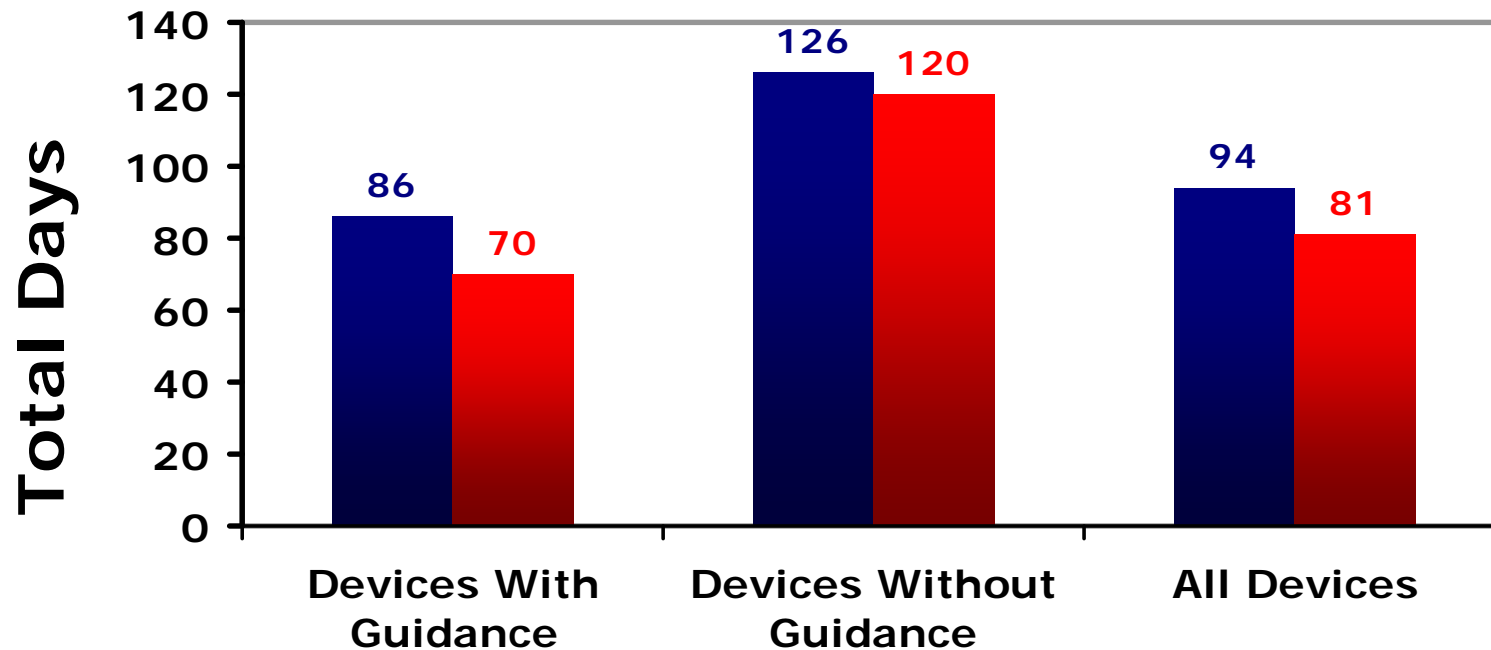


Third Party Reviews

Elements of Third Party Reviews Most Commonly Found Deficient (Based on Recent Reviews)

- **Summary of device characteristics, intended use, performance, and reason for 510(k)**
- **Comparison to legally marketed devices — identification and analysis of key similarities & differences**
- **Rationale for conclusions and recommendations**

*Comparison of Average Total Elapsed Days from 510(k)
Receipt to FDA Decision
- Excluding "Special" 510(k)s -
(FY 2005 Receipts)*



510(k)s Reviewed By: ■ FDA* ■ 3rd Party**

* Comparable 510(k)s reviewed entirely by FDA (same product code)

** Includes time for third party's review and FDA's assessment



Program Experience

Successes

- Industry use of third parties has increased (but still only 13% of eligible 510(k)s)
- On average, third party process has yielded more rapid 510(k) decisions
- Results have been most positive for devices with FDA device-specific guidance document and high volume of third party reviews (e.g., diagnostic ultrasound)



Program Experience

Challenges

- **About half of initial third party reviews are not acceptable, significantly more for devices without an FDA guidance document**
- **Training and ensuring consistency are challenging due to lack of third party access to FDA's precedent files and internal databases**
- **Overall, section 523 has not reduced FDA resource needs**



FDA's Third Party Web Page

- **Procedural guidance**
- **List of eligible devices**
- **List of Accredited Persons**

www.fda.gov/cdrh/thirdparty



Questions?

- FDA's third party web page:
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- Eric Rechen, ODE/CDRH:
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Thank you!

www.fda.gov/CDRH

