510(k)
Third Party Reviews

Eric Rechen

Policy Analyst

Program Operations Staff

FDA Office of Device Evaluation

CDRH

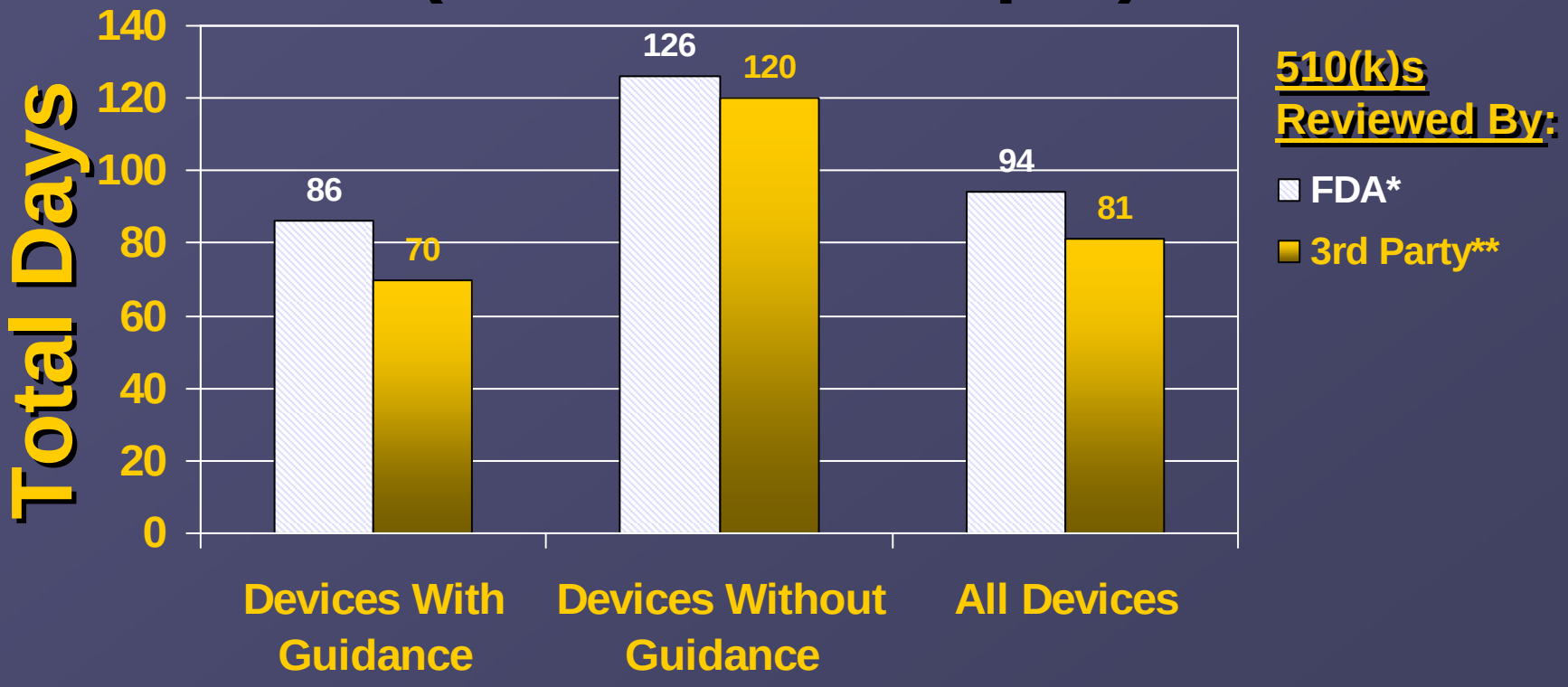
Third Party Review Program *(a.k.a. "Accredited Persons Program")*

- 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

Purpose

- More rapid decisions
- Better allocation of FDA's resources

Comparison of Average Total Elapsed Days for 510(k) Reviews
- Excluding "Special" 510(k)s - (FY 2005 Receipts)



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

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

Use of Third Parties

- Approximately 300 “third party” 510(k)s in FY 2008
- 8% of all 510(k)s

How Does It Work?

Third Party (TP) Review Process

- Applicant may elect to use TP or FDA for eligible devices
- If TP route is chosen:
  - Applicant contracts with TP
  - TP reviews 510(k), makes recom.
  - FDA issues final decision (30 days)

FDA's Third Party Web Page
www.fda.gov/cdrh/thirdparty

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

Which Devices Are Eligible?

Eligible Devices

- More than 670 eligible Class I and Class II device types
- 60% of all 510(k) submissions
- Eligible device list accessible from: *www.fda.gov/cdrh/thirdparty*

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**

Statutory Limitation
§ 523(a)(3)

Third parties also may not review:

- **510(k)s that require CBER/CDER lead or consulting review.**

  Example:
  (e.g., drug/device combination products)

Who Are the Third Parties?

Accredited Organizations

- 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.

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

Why Consider a Third Party?

- Usually more timely
- Many TPs also have standards expertise and foreign regulatory role
- Accessibility
- No FDA user fee

When to Think Twice

- Complex, precedent-setting submissions
- Device eligibility uncertain (e.g., may require clinical data)
- “Special” 510(k)s
- TP lacks relevant experience

Questions?

- FDA's third party web page:
  www.fda.gov/cdrh/thirdparty
- Eric Rechen, ODE/CDRH:
  301-796-6562
  eric.rechen@fda.hhs.gov
- 510(k) Staff, ODE/CDRH
  301-796-5640
- DSMICA
  800-638-2041
  dsmica@fda.hhs.gov