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)

510(k)s Reviewed By:

- FDA*
- 3rd Party**

<table>
<thead>
<tr>
<th>Total Days</th>
<th>Devices With Guidance</th>
<th>Devices Without Guidance</th>
<th>All Devices</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>86</td>
<td>126</td>
<td>94</td>
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<tr>
<td></td>
<td>70</td>
<td>120</td>
<td>81</td>
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* 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](http://www.fda.gov/cdrh/thirdparty)

- Eric Rechen, ODE/CDRH: 301-796-6562
  [eric.rechen@fda.hhs.gov](mailto:eric.rechen@fda.hhs.gov)

- 510(k) Staff, ODE/CDRH
  301-796-5640

- DSMICA
  800-638-2041
  [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov)