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510(k) Third Party Review Program

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Agenda

• Objectives
• Background
• Eligibility Factors for Devices
• How 510(k) Third Party (3P510k) Review Organizations should review files
• Recognition and Rerecognition of 3P510k Review Organizations
• Suspension or Recognition Withdrawal
• Leveraging International Harmonization
Objectives

• Provide an overview of the 510(k) Third Party Review Program

• Identify eligible devices

• Recognize elements of an FDA-equivalent review

• Review key actions for 3P510k Review Organizations
Background

Delivers on MDUFA IV Commitment

Replaces Previous 3P510k Guidances
The Review Organization Interacts with Submitters on the FDA’s Behalf
The Program Protects & Promotes Public Health

Enhance Speed to Market
With a voluntary alternative review process

Focus FDA Resources
On higher risk & complex devices

Maintain Confidence
In safety & effectiveness of lower risk & less complex devices
Program Updated to Eliminate Routine Re-Review

• Product code eligibility updated to support success
• 3P510k Review Organizations perform FDA-equivalent reviews
• 3P510k Review Organization recognition sunsets every 3 years
Reviewing the Right Devices

- No major safety signals
- Well-understood
- Lower risk

See Section V of the guidance for more detail

www.fda.gov
Half of all 510(k)s submitted to CDRH are eligible for 3P510k review.

See Section V of the guidance for more detail.
We Expect FDA-Equivalent Reviews

1. Ensure device is eligible
2. Assign qualified reviewers
3. Use relevant guidances & information
4. Interact Early with the FDA
5. Review, document & submit to the FDA

See Section VI of the guidance for more detail
FDA-Equivalent Reviews Explain their Analysis and Recommendation

• Review and assess the submission
  – How do you assess the regulatory question of substantial equivalence?
  – Assess ‘how’ rather than state that a standard or guidance was used

• Organize and submit to the FDA
  – Be sure to include a useful Table of Contents
  – Update the review memo to reflect deficiencies and their resolution

See Section VI of the guidance for more detail
See “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”
3P510k Submitters and Review Organizations Have the Same Rights for Dispute Resolution

• Many disputes are often the results of misunderstanding or miscommunication – seek clarification first
• Center for Devices and Radiological Health Appeals Processes
• Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A
• Complaints can be sent to 3P510k@fda.hhs.gov
Leveraging Global Standards is Least Burdensome

Organizational Behaviors

Good Regulatory Review Practices

MDSAP N3

GRRP N40

See Section X of the guidance for more detail

Link to these documents on Resources Slide #21

www.fda.gov
Main takeaway:
- quality, well-documented, FDA-equivalent reviews

(A) Submissions, communications, and all documentation should be in English

(B) Impartiality, including not promising FDA clearance
- See also IMDRF N3

(C) Training and expertise of review personnel
- Leverages IMDRF N40

(D) Controls and records for using external technical expertise

(E) Maintain confidentiality

(F) Complaint handling

(G) Recordkeeping

See Section VII of the guidance for more detail
We Clarified Suspension and Withdrawal of Recognition

• The act provides exact language in 301(y)(1) for prohibited acts
• We expect 3P510k Review Organizations to demonstrate technical competency
• We will assess and audit 3P510k Review Organizations periodically as necessary
• If needed, we will suspend or withdraw recognition after providing notice and an opportunity for an informal hearing

See Section IX of the guidance for more detail
Follow Good Business Practices

- Document & record
- Be aware of prohibited acts
- Maintain quality reviews

See Section VII & IX of the guidance for more detail
Current 3P510k Review Organizations Should Submit Applications to be Recognized by September 12, 2020

- All entities will go through the new recognition process
- Work proactively on your recognition
- Submit your application as soon as practical
- All recognitions sunset after 3 years
What You Should Include in Your Application to be a Recognized 510(k) Third Party Review Organization

(1) Administrative Info, including device types
(2) Policies and procedures to prevent conflicts of interest
(3) Personnel qualifications
   – Including supervisory personnel
(4) Certification statements

See Section VIII of the guidance for more detail
Also available at FDA.gov
https://www.fda.gov/medical-devices/510k-third-party-review-program/how-become-third-party-review-organization
The FDA Will Monitor & Audit

- Training
- Recognition
- Feedback
- Review
- Monitor
- Audit

12 to 18 months after recognition

3P510k Review Organization
Resources

• 510(k) Third Party Review Program: Final Guidance
  – https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program

• 510(k) Third Party Review Program Webpage
  – https://www.fda.gov/medical-devices/premarket-submissions/510k-third-party-review-program

• CDRH Learn Modules for the 510(k) Third Party Review Program
  – https://www.fda.gov/training-and-continuing-education/cdrh-learn#collapseSeven

• Product Code Classification Database

• Federal Food, Drug, and Cosmetic Act

• IMDRF MDSAP Working Group N3 Final: 2016 (Edition 2): “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”

• IMDRF/GRRP WG/N40 Final:2017: “Competence, Training, and Conduct Requirements for Regulatory Reviewers”
Questions?

Division of Industry and Consumer Education: DICE@fda.hhs.gov

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http://www.fda.gov/training/cdrhlearn

Under Heading: 510(k) Third Party Review Program

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