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510(k) Third Party Review Program

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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 16, 2020

Agenda

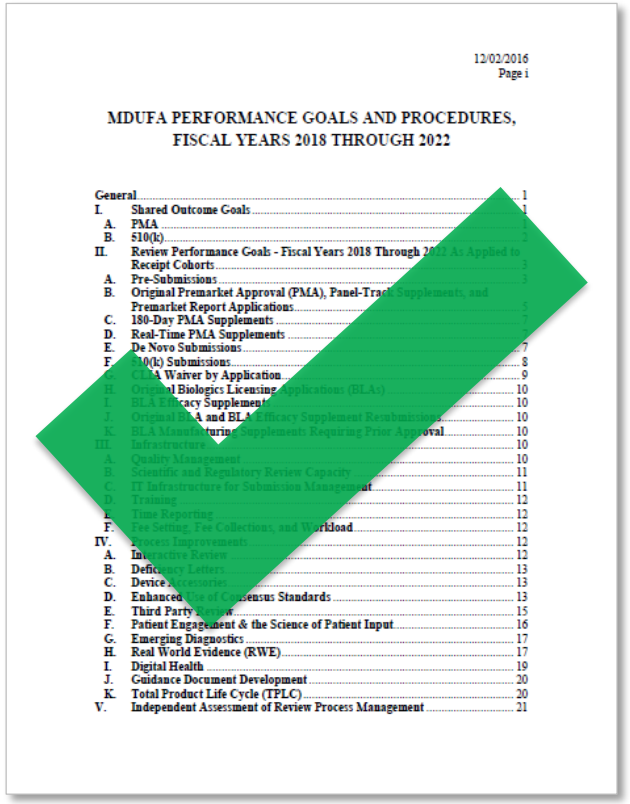
- Objectives
- Background
- Eligibility Factors for Devices
- How 510(k) Third Party (3P510k) Review Organizations should review files
- Recognition and Rerecognition of 3P510k Review Organizations
- Suspension or Recognition Withdrawal
- Leveraging International Harmonization

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



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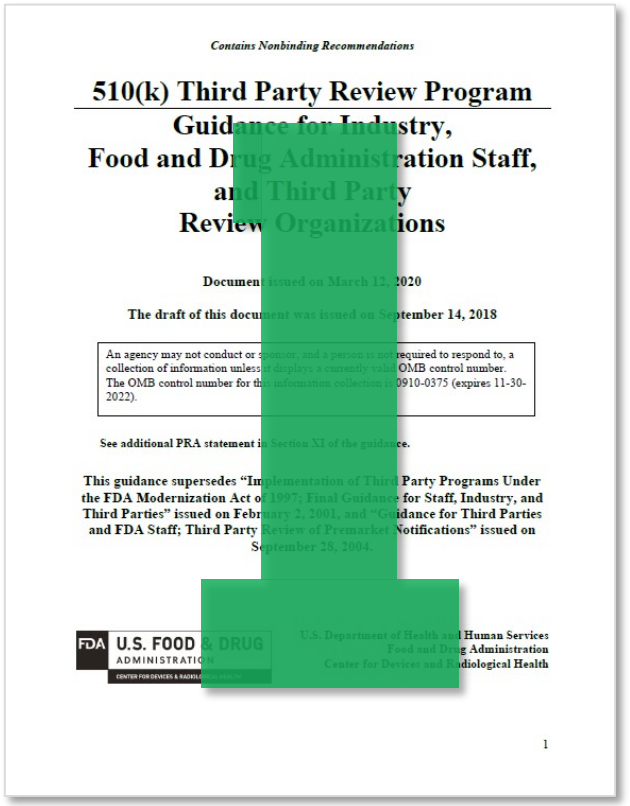
Page i

MDUFA PERFORMANCE GOALS AND PROCEDURES,
FISCAL YEARS 2018 THROUGH 2022

Replaces
Previous 3P510k Guidances



Contains Nonbinding Recommendations

510(k) Third Party Review Program
Guidance for Industry,
Food and Drug Administration Staff,
and Third Party
Review Organizations

Document issued on March 12, 2020

The draft of this document was issued on September 14, 2018

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0375 (expires 11-30-2022).

See additional PRA statement in Section XI of the guidance.

This guidance supersedes "Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties" issued on February 2, 2001, and "Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications" issued on September 28, 2004.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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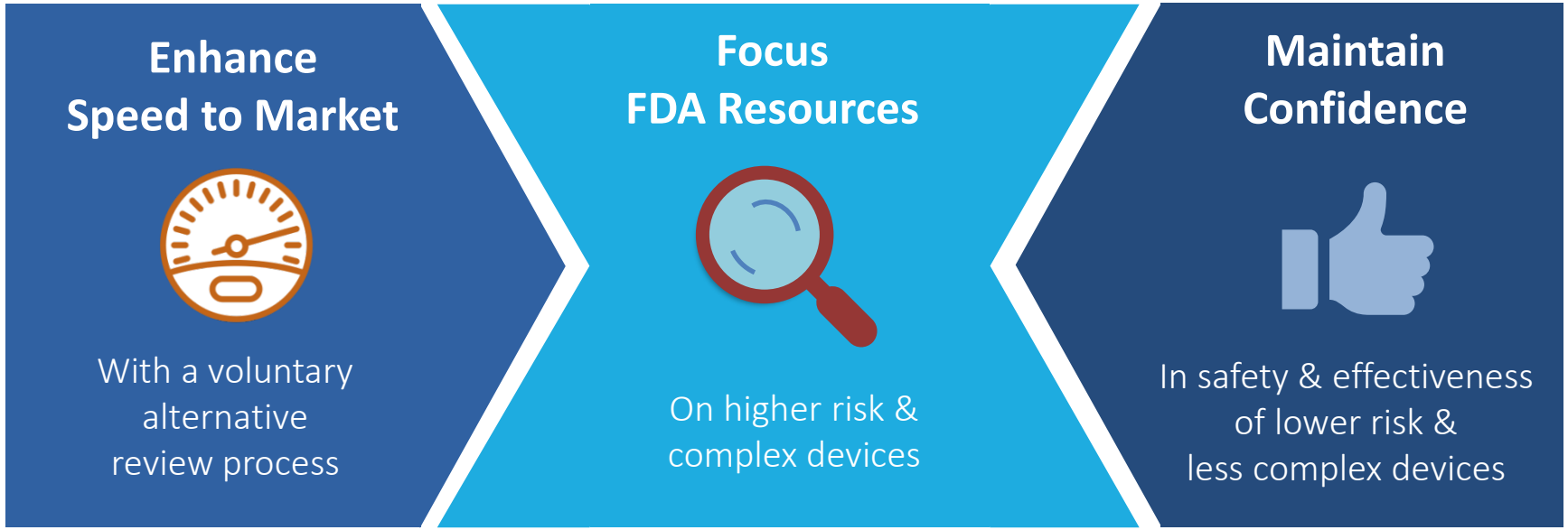
The Review Organization Interacts with Submitters on the FDA's Behalf

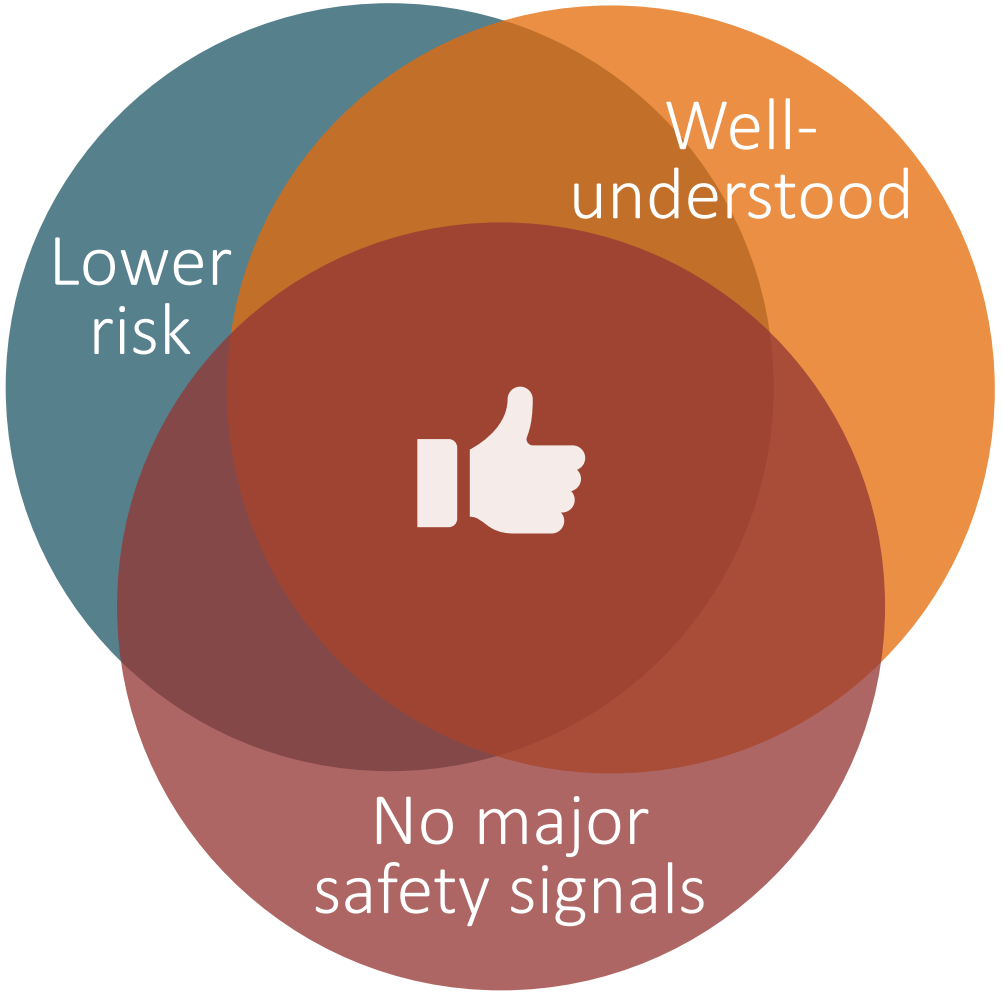
The Program Protects & Promotes Public Health



Program Updated to Eliminate Routine Re-Review

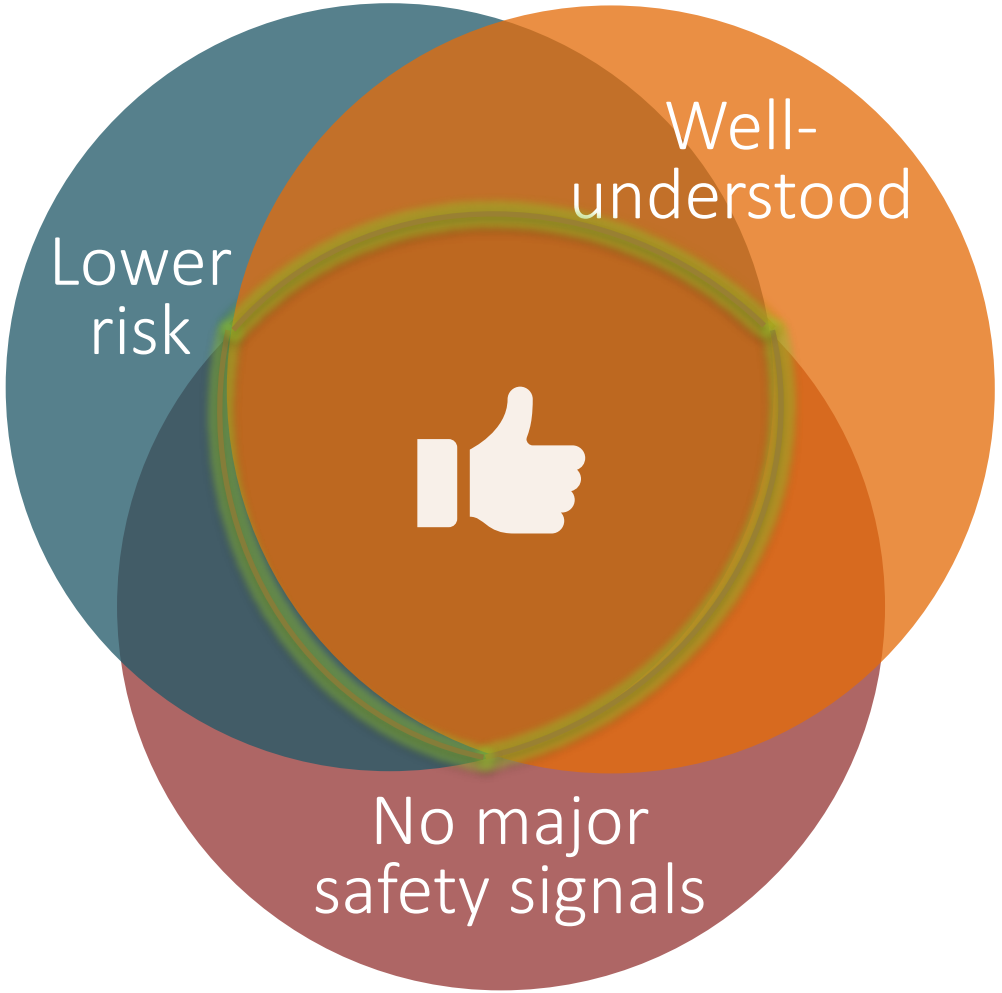
- Product code eligibility updated to support success
- 3P510k Review Organizations perform FDA-equivalent reviews
- 3P510k Review Organization recognition sunsets every 3 years

Reviewing the Right Devices



See Section V of the guidance for more detail

Reviewing the Right Devices cont.



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

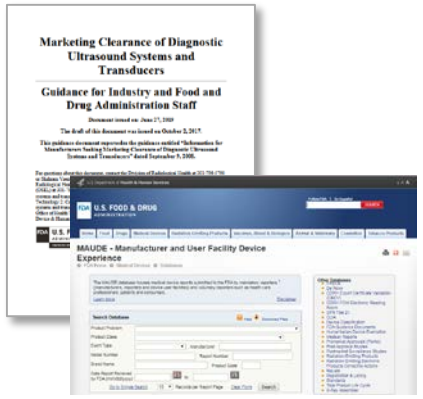
See Section V of the guidance for more detail

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)]”
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k

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

MDSAP N3

Good Regulatory Review Practices

GRRP N40

IMDRF International Medical Device Regulators Forum

See Section X of the guidance for more detail
Link to these documents on Resources Slide #21

We Clarified Our Expectations of 3P510k Review Organizations

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

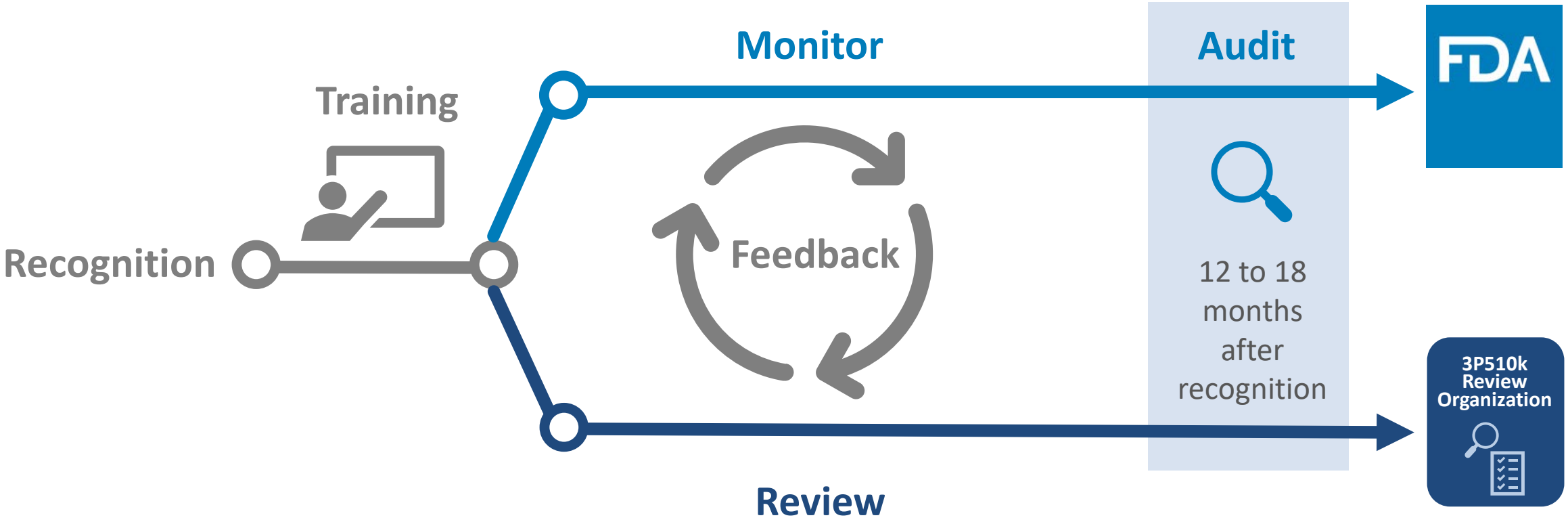
(3) Personnel qualifications

- 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



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
  - https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database
- Federal Food, Drug, and Cosmetic Act
  - https://legcounsel.house.gov/Comps/Federal Food, Drug, And Cosmetic Act.pdf
- IMDRF MDSAP Working Group N3 Final: 2016 (Edition 2): “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”
  - http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160324-requirements-auditing-orar.pdf
- IMDRF/GRRP WG/N40 Final:2017: “Competence, Training, and Conduct Requirements for Regulatory Reviewers”
  - http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf

Questions?

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

Slide Presentation, Transcript and Webinar Recording will be available at:

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

Under Heading: 510(k) Third Party Review Program

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