A New Way to 510(k): The Safety and Performance Based Pathway

FDA Small Business Regulatory Education for Industry (REdI)

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Why Are We Doing This?

Modernize our approach to promote greater transparency and enhance device safety

Learning Objectives

1. Summarize the current 510(k) program
2. Outline the Safety and Performance Based Pathway
3. Describe the development of performance criteria
4. Discuss submitting a 510(k) to the Safety and Performance Based Pathway

510(k) Basics

What is a 510(k)?

A premarket submission to demonstrate that a device is *as safe and effective* (**substantially equivalent**) to a *legally marketed device* (**predicate device**)

What is a Predicate Device?

- Legally marketed prior to May 28, 1976
- Reclassified from Class III to Class II or I
- A device which has been found substantially equivalent through the 510(k) process
- Granted marketing authorization via the De Novo classification process

What is Substantial Equivalence?

- New device and predicate device have same intended use:
  - Same technological characteristics; **or**
  - Different technological characteristics that don't raise different questions of safety and effectiveness; **and** information submitted to FDA demonstrates that the device is as safe and effective as the predicate device
- 510(k) devices are FDA-cleared and NOT FDA-approved

Current 510(k) Pathways

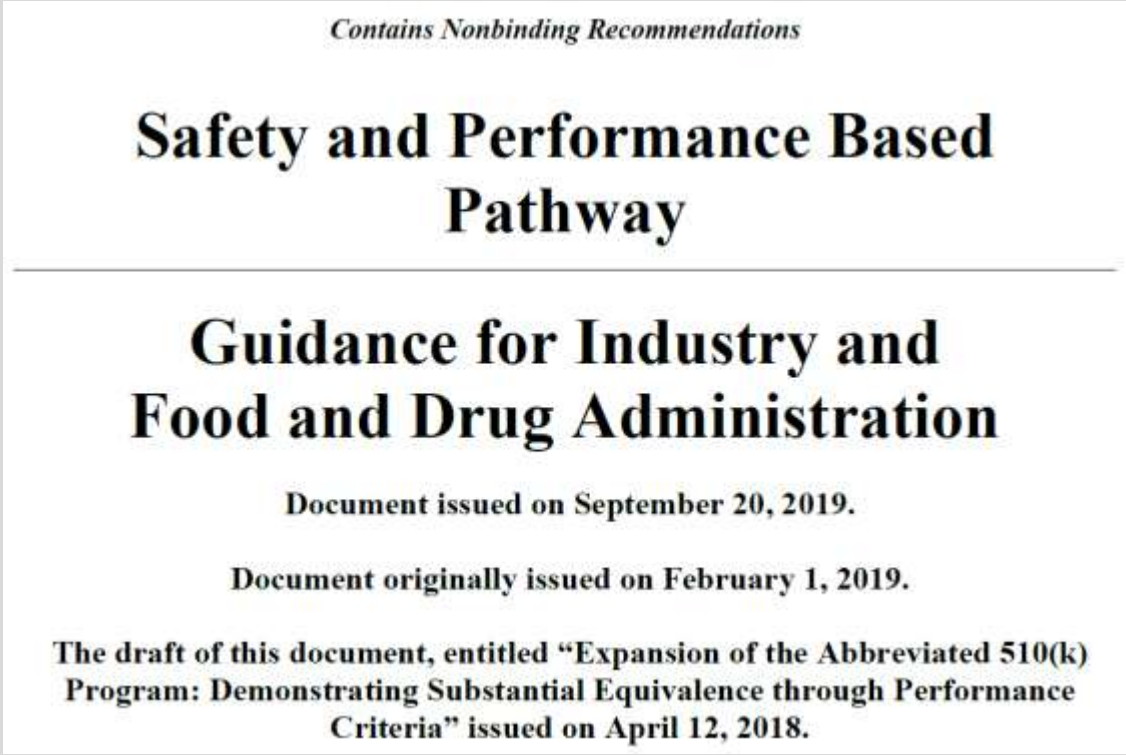
- Traditional
  - Most common 510(k) pathway to get device on the market
- Special
  - Used for certain changes to your own FDA-cleared device
- Abbreviated
  - Leverages use of summary reports based on guidance, special controls, and/or consensus standards

Room for Improvements

- Need for increased transparency of recommended testing
- Potential lack of predicate availability to conduct side-by-side assessment
- Opportunity for more predictable and efficient review process

Safety and Performance Based Pathway

Final Guidance



Contains Nonbinding Recommendations

Safety and Performance Based Pathway

Guidance for Industry and Food and Drug Administration

Document issued on September 20, 2019.

Document originally issued on February 1, 2019.

The draft of this document, entitled "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria" issued on April 12, 2018.

www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

Safety and Performance Based Pathway

- **Voluntary** 510(k) pathway for well-understood Class II devices that meet specified performance criteria
- Device would meet FDA-identified performance criteria used to demonstrate substantial equivalence
- Direct and transparent approach to demonstrating the safety and effectiveness of low to moderate risk devices

Device-Specific Guidances

- Appropriate devices are within scope of guidance
  - Regulation, product code, indications for use, etc.

- Cross-cutting recommendations largely the same and consistent with previous subject guidance(s)
  - Biocompatibility, sterility, electrical safety, etc.

Performance Criteria

- FDA intends to identify the performance criteria for each device type eligible for the pathway in guidance
- FDA intends to recommend testing methods where feasible
- FDA intends to ensure that criteria represent performance levels that are at least equivalent to the performance of legally marketed devices

Key Points

- Predicate device needs to be identified
- Scope of appropriate devices and performance criteria identified in guidance
- **All** criteria should be met
- List of device-specific guidances for the pathway can be found on FDA's webpage

Development of Performance Criteria

How to Develop Performance Criteria?

- Derived from multiple sources including:
  - FDA-recognized consensus standards
  - FDA guidance
  - Scientific literature
  - Historical 510(k) submission data
- Only performance criteria in FDA-recognized consensus standards that have been identified in FDA guidance can be used in this pathway

Review of Data

Type of Performance Criteria and Methodology FDA identified in the relevant Safety and Performance Based Pathway Guidance		Safety and Performance Based Pathway 510(k) Submission should Include
Performance Criteria	***Testing Methodology***	
FDA-recognized standard	FDA-recognized standard	Declaration of Conformity[1]
FDA-established	FDA-recognized standard	Results Summary[2] and Declaration of Conformity[1]
FDA-established	FDA-recommended or specified	Results Summary[2] and Testing Protocol[2]
FDA-established	None specified/recommended or alternative to FDA-specified methodology used	Complete Test Report[2]

(1) www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices
(2) www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

Stakeholder Engagement

- Submit comments/suggestions
  - On device-specific draft guidances with test method and performance criteria feedback
  - Device types well-suited for inclusion in pathway to safety and performance based pathway final guidance docket (FDA-2018-D-1387)
  - Standardized methods and criteria for the FDA to evaluate

Submitting a 510(k)

Is Your Device Appropriate?

- New device should be within the scope of a device-specific technical guidance for the pathway

- Only **final** (not draft) device-specific technical guidances can be implemented for the pathway

Elements of 510(k) Review

- Same 90 day review timeline
- Consistent with Refuse to Accept (RTA) processes
  - Similar to the Abbreviated RTA Checklist
- 510(k) conversion
- Substantive Interaction same as Traditional and Abbreviated 510(k)

Key Points

- Recommend cover letter state that the submission is for the Safety and Performance Based Pathway
- If you are unsure if your device is appropriate:
  - Contact Division of Industry and Consumer Education (DICE) at DICE@fda.hhs.gov
  - Request pre-submission (Q-Sub) feedback (it's free!)

Knowledge Check

Knowledge Check

A predicate device does not need to be identified in a Safety and Performance Based 510(k).

1. True
2. False

Knowledge Check

All performance criteria should be met to utilize the Safety and Performance Based Pathway.

1. True
2. False

Knowledge Check

Within how many days will FDA usually make a Safety and Performance 510(k) determination?

1. 30
2. 60
3. 90

Summary

- State of the 510(k) program and areas for improvement
- Described the framework of the Safety and Performance Based Pathway
- Transparent performance criteria and test methods
- Expectations for submitting a 510(k) to the new pathway

Resources

Slide Number	Cited Resource	URL
5	510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]	www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k
8	Abbreviated 510(k) Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program
8	Special 510(k) Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program
11	Safety and Performance Based Pathway	www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway
15	Framework for the Safety and Performance Based Pathway	www.fda.gov/medical-devices/premarket-notification-510k/framework-safety-and-performance-based-pathway

Resources cont.

Slide Number	Cited Resource	URL
18	Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices [(1)]	www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices
18	Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions [(2)]	www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket
22	Refuse to Accept Policy for 510(k)s	www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks
23	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

Questions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