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Safety and Performance Based Pathway

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Agenda

- Objectives
- Background
- Safety and Performance Based Pathway final guidance
- Device-specific performance criteria draft guidances
- 510(k) submission to Safety and Performance Based Pathway
- Future plans
- Opportunities for stakeholder engagement

Objectives

- Provide an overview of the Safety and Performance Based Pathway

- Outline content and use of device-specific guidance documents

Initiatives to Enhance Device Safety

- April 2018 - Medical Device Safety Action Plan released

- November 2018 – Joint statement by Drs. Scott Gottlieb and Jeffrey Shuren
  - Modernizing the 510(k) Pathway
  - Promoting greater transparency and post-market surveillance

Current 510(k) Program

- The 510(k) program has undergone a number of statutory changes since its inception

- The U.S. Food and Drug Administration (FDA) has adapted its implementation of the program in response to changing statutory requirements and the evolving medical device landscape

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.

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

Safety and Performance Based Pathway

- Voluntary 510(k) pathway for certain well-understood FDA-specified Class II devices to gain clearance for marketing based on demonstrating they 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 certain, well understood devices

Performance Criteria

- Through guidance, the FDA will identify the performance criteria for each device type appropriate to be reviewed through the Safety and Performance Based Pathway, as well as the testing methods recommended where feasible, and any other relevant information.

- The FDA will ensure that these criteria represent performance levels that are at least equivalent to the performance of legally marketed devices of the type to which they apply.

Performance Criteria (cont.)

- Performance criteria may be derived from multiple sources including FDA-recognized consensus standards, the FDA's guidance, scientific literature, and historical 510(k) submission data.

- Performance criteria in FDA-recognized consensus standards that have not been identified in a Safety and Performance Based Pathway device-specific guidance should not be used in this pathway.

Using the Safety and Performance Based Pathway

- The new device should meet all of the identified criteria
  - Unique to this pathway
- Identification of an appropriate predicate is still necessary
- Performance criteria are appropriate when:
  - Indications and technical characteristics do not raise different questions of safety and effectiveness than the predicate
  - Performance criteria align with one or more predicates of the same device type
  - The new device meets all of the identified criteria in device-specific S&P guidance

Using the Safety and Performance Based Pathway (cont.)

- Indications and technical characteristics do not raise different questions of safety and effectiveness than the predicate
  - Focus on the decision point that requires a 510(k) submitter to demonstrate that, despite technological differences, its device is as safe and effective as a legally marketed device
  - Ensure the criteria are appropriate by clarifying the set of devices for which the performance criteria are appropriate in guidance and having submitters identify a predicate of the same device type

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) Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
2) Recommended Content and Format of Non-clinical Bench Performance Testing Information in Premarket Submissions

Device-specific Performance Criteria Guidances

- Currently 4 device-specific draft guidances with more in development
- Pathway will not be implemented until at least one guidance is finalized
- Criteria development
  - When possible, we reference existing FDA-recognized standards for both methodology and performance criteria
  - When historical 510(k) data is used, the FDA intends to look at recent predicates to establish the performance of more modern devices and technologies
  - Some criteria may be qualitative, such as biocompatibility

Device-specific Performance Criteria Guidances (cont.)

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

- Cross-cutting recommendations largely the same and consistent with current cross-cutting guidance(s)
  - Biocompatibility
  - Sterility
  - Reprocessing
  - Electrical Safety and Electromagnetic Compatibility
  - Software

Safety and Performance Device Type List Modifications

- The FDA intends to maintain a list of device types on our website, accompanied by links to associated guidances

- The FDA intends to revise the list to add or remove device types and may revise performance criteria and testing methodology over time as necessary
  - Periodic review of the applicable criteria and guidances to ensure they remain contemporary

Safety and Performance Device Type List Modifications (cont.)

- May modify or remove an entry from the list, particularly where new information indicates that the performance criteria in the identified guidance do not fully support a substantially equivalent (SE) determination

- Changes to the list, such as, when a device type is removed from the list or an updated final guidance is issued, would apply prospectively to devices for which a 510(k) has not yet been submitted

510(k) Submission to the Safety and Performance Based Pathway

- Pre-Submission
  - Can be used to determine if device is appropriate for the pathway
  - On a case-by-case basis and if otherwise in scope, can be used if you determine there is additional testing outside of the guidance that is necessary to demonstrate safety and performance of the device
- Refuse to Accept (RTA) similar to Abbreviated 510(k)
  - Consistent with Refuse to Accept Policy Guidance
- 90-Day Review clock
- Substantive Interaction same as Traditional and Abbreviated 510(k)

Future Plans

- Receive and consider comments to public dockets
- Finalize the first set of technical device-specific performance guidances to implement the pathway
- Continue development of device-specific draft guidances across the Center for Devices and Radiological Health (CDRH)

Stakeholder Engagement

- Stakeholders including the FDA, patient groups, and industry should collaborate to:
  - Identify device types that may already be a good fit for the pathway
  - Collaborate to facilitate the FDA's recognition of standards by identifying methods or criteria that are acceptable
  - Identify gaps or challenges that may limit the appropriateness of device types
  - Harmonize with other regulatory jurisdictions if they have established methods or criteria that could be utilized, but are not currently

Stakeholder Engagement (cont.)

- Submit comments on device-specific guidances with device-specific feedback or general programmatic feedback

- Submit suggestions of device types well suited for inclusion in pathway, as well as suggestions of standardized methods and criteria for the FDA to evaluate, to Safety and Performance Based Pathway final guidance docket:

  FDA-2018-D-1387

Resources

- Safety and Performance Based Pathway Webpage
- Safety and Performance Based Pathway final guidance
- Draft Device-specific guidances
  - Cutaneous Electrodes for Recording Purposes
  - Conventional Foley Catheters
  - Orthopedic Non-Spinal Metallic Bone Screws and Washers
  - Spinal Plating Systems
- Recommended Content and Format of Non-clinical Bench Performance Testing Information in Premarket Submissions
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices

Questions?

Division of Industry and Consumer Education:
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http://www.fda.gov/training/cdrhlearn

Under Heading: How to Study and Market Your Device;
Subheading: Premarket Notification

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