Framework for the Safety and Performance Based Pathway

Overview

There are three types of Premarket Notification 510(k)s that may be submitted to FDA: Traditional; Special; and Abbreviated. The Special and Abbreviated 510(k) programs were developed in 1998 and described in the "New 510(k) Paradigm" to facilitate the 510(k) review process for certain types of submissions subject to 510(k) requirements. In 2019, the FDA split "The New 510(k) Paradigm" into separate guidance documents; The Special 510(k) Program and The Abbreviated 510(k) Program. The Safety and Performance Based Pathway is an expansion of the concept of the Abbreviated 510(k) pathway for certain, well understood device types.

The FDA expects to operationalize this pathway once the first device types and applicable performance criteria have been identified and final guidances have been published. Once the FDA begins to operationalize this pathway, a medical device manufacturer will be able to meet FDA-identified performance criteria to demonstrate that its device is as safe and effective as a predicate device. The use of this pathway does not affect the FDA's ability to obtain any information authorized by the statute or regulations.

For more information refer to the guidance Safety and Performance Based Pathway.

As a first step towards operationalizing of the Safety and Performance Based Pathway, the FDA issued draft guidances on September 19, 2019, identifying performance criteria and testing methodologies for certain devices within four class II device types. The FDA is soliciting feedback on these guidances, which will be used to finalize these draft guidances as well as help expand this pathway to other types of devices. Submit comments on the draft guidances at www.regulations.gov using the following docket numbers.

- Spinal Plating Systems
  - Submit comments on spinal plating system draft guidance (docket FDA-2019-D-1647)
- Cutaneous Electrodes for Recording Purposes
  - Submit comments on cutaneous electrodes draft guidance (docket FDA-2019-D-1649)
- Conventional Foley Catheters
  - Submit comments on conventional Foley catheters draft guidance (docket FDA-2019-D-1651)
- Orthopedic Non-Spinal Metallic Bone Screws and Washers
  - Submit comments on orthopedic non-spinal metallic bone screws and washers (docket FDA-2019-1652)

What device types are appropriate for the Safety and Performance Pathway?

The Safety and Performance Based Pathway is appropriate when FDA has determined that:

- The new device has indications for use and technological characteristics that do not raise different questions of safety and effectiveness than the identified predicate, and the predicate is within the scope of the list of device types appropriate for the Safety and Performance Based Pathway;
- The performance criteria align with the performance of one or more legally marketed devices of the same type as the new device; and
- The new device meets all the FDA-identified performance criteria.

If any of the above factors are not met, the submitter has the option to submit a Traditional, Special or Abbreviated 510(k).

The FDA will issue future final guidance(s) to apply this Safety and Performance Based Pathway to certain types of devices with corresponding FDA-identified performance criteria. Industry may suggest device types for which the FDA should consider identifying performance criteria. For example, industry may suggest devices for which there are comprehensive FDA-recognized consensus standards. We encourage industry and other stakeholders to submit evidence-based suggestions on what the performance criteria should be for eligible device types. Input can be provided using the docket number FDA-2018-D-1387 at www.regulations.gov.

The FDA intends to maintain a list of device types appropriate for the Safety and Performance Based Pathway on this website, accompanied by the guidance documents that identify the performance criteria for each device type, as well as the testing methods recommended in the guidances where feasible, and any other relevant information.

Content of a Safety and Performance Based 510(k)

The amount and type of information necessary to support a finding of substantial equivalence under the Safety and Performance Based Pathway will depend on the underlying source for the performance criteria and testing methods. Table 1 and the Appendix within the Safety and Performance guidance summarize the types of information that would be included in a submission based on the submitter's approach.

Importantly, 510(k) submitters still need to identify a predicate for certain aspects of substantial equivalence. However, instead of conducting direct comparison testing to demonstrate that a device is as safe and effective as a predicate device despite technological differences, manufacturers will be able to use this pathway, when appropriate.

More information on content that would be included within a Safety and Performance Based 510(k) will be available in the device-specific guidances that will be issued.

Resources

- Safety and Performance Based Pathway
- How to Prepare an Abbreviated 510(k)
- Format for Traditional and Abbreviated (510(k)s)
- The Special 510(k) Program

Content current as of:
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Regulated Product(s)
Medical Devices