(Don't) Take The Long Way Home: FDA Issues Draft Guidance on Expansion of the Abbreviated 510(k) Program

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The Food and Drug Administration channeled, in the other direction, the 1979 Supertramp song, "Take the Long Way Home," after it issued a draft guidance entitled, "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria; Draft Guidance for Industry and Food and Drug Administration Staff."[1] While not legally binding, the draft provides the agency's current thinking on how companies may use the Abbreviated 510(k) regulatory pathway to obtain marketing authorization for certain types of medical devices in a more time-effective manner. One notable point is that the new option may allow a company to submit an Abbreviated 510(k) and not have to rely on whether a direct comparison to a predicate device must be shown to demonstrate substantial equivalence. The pathway is intended to "allow more flexibility to use more modern criteria as the reference standard and permit comparisons to standards that more closely approximate the kind of current technology," according to FDA Commissioner Scott Gottlieb.[2]

This Bulletin summarizes many of the highlights of the draft guidance, comments to which are due to FDA by July 11, 2018.

Highlights

- The Abbreviated 510(k) submission relies on the use of FDA guidance documents, established special controls, and FDA-recognized consensus standards to demonstrate some of the performance characteristics necessary to support a finding of substantial equivalence
    - for this optional Expanded Abbreviated 510(k) program, an applicant would use these mechanisms to demonstrate <u>all</u> of the performance characteristics necessary to support a finding of substantial equivalence for a particular device type
- FDA noted that use of performance criteria is only appropriate when the agency has found that:
    1. the new device has indications for use and technological characteristics that do not raise different questions of safety and effectiveness than the identified predicate;
    2. the performance criteria align with the performance of one or more legally marketed devices of the same type as the new device; and
    3. the new device meets the performance criteria
- If a device cannot rely <u>entirely</u> on performance criteria identified by FDA to demonstrate substantial equivalence for its submission, it is <u>not</u> appropriate for the Expanded Abbreviated 510(k) program

1 83 Fed. Reg. 15847 (April 12, 2018)
2 https://blogs.fda.gov/fdavoice/index.php/2017/12/advancing-policies-to-promote-safe-effective-medtech-innovation/

- For submissions using the Expanded Abbreviated 510(k) program, FDA will continue to require the identification of a predicate device for the intended use and technological characteristics necessary to demonstrate substantial equivalence

- FDA recommends that a company use the Q-Submission program if it has a question about whether a new device may qualify for an Expanded Abbreviated 510(k)

- FDA intends to maintain a list of devices appropriate for the Expanded Abbreviated 510(k) program on its website, with the guidance documents that identify the performance criteria for each device type, the testing methods recommended in the guidance where feasible, and any other relevant information

- FDA recommends that, to demonstrate a device meets the relevant performance criteria, a company should include, where applicable:

    - a declaration of conformity to the standard
    - a summary report recommended in any relevant device-specific guidance; and
    - underlying data demonstrating that the new device meets the FDA-identified performance criteria

- When performance criteria and testing methodologies are provided in an FDA-recognized standard, and the applicant uses those methods to establish that the device meets the performance criteria, the applicant should submit a declaration of conformity

- When FDA establishes performance criteria, through guidance or special controls (or both), and recommends or specifies testing methodologies, and the applicant uses that method, it should submit a summary of the data

- When FDA establishes performance criteria, through guidance or special controls (or both), and recommends or specifies the use of testing methodologies from an FDA-recognized standard, an applicant that uses the methodology should provide a summary of the data, in addition to a declaration of conformity

- If a company chooses to use the Expanded Abbreviated 510(k) program, FDA does not expect it to provide direct comparison testing against a legally-marketed device for performance specifications

- FDA recommends that an applicant of an Expanded Abbreviated 510(k) include information relating to the proposed labeling, sterilization and shelf life, biocompatibility, software, electromagnetic compatibility and electrical safety, and performance testing, except that FDA will not expect the information to describe direct comparison testing against the predicate device

AGG Observations

- While FDA intends to release information on which devices will be eligible for this program, that information is not yet available; therefore, it is difficult to predict which devices could utilize this pathway.

- This pathway is only intended for “mature” devices, i.e., those for which FDA can identify safety and performance criteria that meet or exceed the performance of existing, legally-marketed devices; thus, while the intent is to make clearances more readily available, this pathway might have limited applicability.

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