FDA Launches Pilot to Expand the Special 510(k) Program

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On October 1, 2018, the Food and Drug Administration (FDA) announced a pilot expansion of the Special 510(k) Program. The Special 510(k) Program was developed to help streamline the 510(k) premarket notification process for certain well-defined product modifications to already cleared medical devices by using the design control requirements of the Quality System Regulations (QSRs). The pilot expansion is significant because additional types of device modifications that once did not qualify for a Special 510(k) premarket notification may now fall within the pilot expansion.

Similarly, on September 28, 2018, FDA published a draft guidance for industry providing a proposed framework for considering whether a new 510(k) is appropriate for review as a Special 510(k) under the pilot program.[1] This Bulletin focuses on the pilot expansion and draft guidance which, while not legally binding, represents FDA's current thinking on the subject.

Background

The QSRs require manufacturers to have a set of requirements and activities for the management of the design and development of medical devices, including documentation of design inputs, risk analysis, design output, test procedures, and verification and validation procedures. In implementing the Special 510(k) Program, FDA determined that it would be appropriate to forgo a review of data typically required to demonstrate substantial equivalence for certain medical device modifications, because manufacturers are required to comply with the design control requirements of the QSRs and conduct verification and validation studies. The rigorous design control procedure and the summary information from the design control process serves as the basis for clearing the device modification and helps streamline the agency's review. To incentivize manufacturers to use the Special 510(k) program, FDA processes a Special 510(k) more quickly than a traditional 510(k), intending to review them within 30 days of receipt.

Summary

The Special 510(k) Program pilot expansion allows additional device modifications to qualify for the more simplified and streamlined Special 510(k) premarket notification process. As initially designed, the Special 510(k) Program was not meant for changes that affect a device's intended use or that altered the device's fundamental scientific technology, e.g., automation of a manual device. However, the pilot program now expands the existing Special 510(k) Program by including certain changes to indications for use and technology that were not initially included within the scope of the Special 510(k) Program.

According to FDA's draft guidance, manufacturers making design or labeling changes (including certain changes to the indications for use) to an already-cleared device can have that device reviewed under the Special 510(k) Program if the following conditions are met:

- The proposed change is made and submitted by the manufacturer authorized to market the existing device;

1 A copy of the draft guidance is available here.

- Performance data are unnecessary or, if necessary, well-established methods are available to evaluate the change being made;[2] and

- FDA can review performance data necessary to support substantial equivalence in a summary or risk analysis format. Complete text reports should not be submitted.

The draft guidance also includes a list of circumstances under which FDA believes it is not appropriate to submit a Special 510(k), *e.g.*, when evaluation of the change(s) to the device involve several different scientific disciplines. All Special 510(k) submissions that are received on or after October 1, 2018, will be included in the pilot program. Notwithstanding the expansion, FDA still intends to process all Special 510(k)s within 30 days of receipt.

AGG Observations

- The pilot expansion follows FDA's draft guidance issued on April 12, 2018, proposing to expand the Abbreviated 510(k) Program, which was developed to help streamline the 510(k) premarket notification process.[3] These actions represent FDA's attempts to provide a more efficient and streamlined 510(k) premarket notification process.

- It is unclear whether there will be an increased volume of Special 510(k) submissions and, if so, whether it will cause a backlog such that FDA will not be able to meet its intended 30-day timeframe for review. However, we are not aware that the Special 510(k) Program is currently creating such a traffic jam.

- Manufacturers should review the criteria in the draft guidance to qualify for a Special 510(k) to determine if any device modifications may fall within the pilot expansion. There may be opportunities for certain companies.

- As with any pilot program and/or draft guidance, we do not yet know exactly how FDA intends to implement this new program or guidance.. However, it does appear that FDA intends to take a step toward expediting the review of certain types of changes, and to utilize the Special 510(k) program to effectuate such reviews. While it remains to be seen how FDA will execute, the pilot program and guidance show that the effort has been made.

Interested stakeholders may submit comments to FDA on the pilot expansion until November 27, 2018. If you have any questions about FDA's Special 510(k) Program or the pilot expansion, or are interested in submitting comments, please contact Alan Minsk, Seth Ray, or Genevieve Razick.

2 According to the draft guidance, well-established methods are those that have been established for evaluation of the device, device type, or scientific topic area, and are validated according to scientific principles.

3 A copy of the draft guidance is available here.

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