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ALERTS

FDA Issues Draft Guidance On Expanding Special 510(k) Program

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The FDA recently released a draft guidance titled "The Special 510(k) Program." According to the draft guidance, its purpose is to describe an optional pathway for certain well-defined device modifications where a manufacturer modifies its own legally marketed medical device, along with rigorous design control procedures that produce highly reliable results that can form – in addition to other 510(k) content requirements – the basis for a finding of substantial equivalence (SE).

The FDA also believes expanding the Special 510(k) Program will help it meet its 510(k) Total Time to Decision (TTD) goals under the Medical Device User Fee Amendments (MDUFA). The guidance states that the FDA intends to process these Special 510(k)s within 30 days of receipt.

The draft guidance proposes to evaluate whether design and labeling changes can be reviewed under a Special 510(k) by focusing on whether the method(s) to evaluate the change(s) are well-established, and whether the results can be sufficiently reviewed in a summary or risk analysis format. A design or labeling change to an existing device (including certain changes to the indications for use) may be appropriate for a Special 510(k) when:

- The proposed change is made and submitted by the manufacturer authorized to market the existing device
- Performance data are unnecessary, or if performance data are necessary, well-established methods are available to evaluate the change
- All performance data necessary to support SE can be reviewed in a summary or risk analysis format

The draft guidance includes the following flow chart summarizing the analysis of when a Special 510(k) is appropriate:

The draft guidance also cautions that other considerations will make it inappropriate to submit a Special 510(k). The additional considerations include:

- When evaluation of the change(s) to the device involve several different scientific disciplines
- For multiple devices with unrelated changes
- When a recent Quality System (QS) inspection has identified observations related to design controls that are relevant to the design changes under review in the 510(k)

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- When Special 510(k)s are submitted for common scenarios that the FDA anticipates a review of, then complete test reports will be necessary to establish SE, such as:
    - Changes to the indications for use that are supported by clinical, animal, or cadaver data
    - Use of novel sterilization methods
    - Changes to introduce initial Magnetic Resonance (MR) Conditional labeling, or significant deviations from the test methods used to establish MR Conditional labeling in the original 510(k)
    - Change from single-use to reusable when reprocessing validation or human factors data should be provided
    - Use of chemical characterization with toxicological risk assessment to address biocompatibility
- For a reprocessed single-use device that requires the submission of cleaning, sterilization, and functional performance validation data
- For changes that could affect the reprocessing of reusable devices

The draft guidance concludes with three appendices addressing the content of a Special 510(k), examples of changes, and examples of the summary of design control activities, respectively.

The FDA is accepting comments on this draft guidance only until Nov. 27.

As always, the FDA's guidance documents do not establish legally enforceable responsibilities, but rather describe the FDA's current thinking on a topic.

For more information, please contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler, chair of the firm's Food, Drug and Device group, at 317-231-7392 or lynn.tyler@btlaw.com. Visit us online at www.btlaw.com/food-drug-and-device-law-practices.