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ALERTS

FDA Fall Fling: Medical Device Guidance Activity Flourishes

October 21, 2019 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | San Diego | South Bend | Washington, D.C.

The FDA closed the federal fiscal year with a flurry of activity by issuing multiple guidance documents on various medical device topics, including 510(k) submissions, de novo petitions, the Safer Technologies Program, and medical device software.

The FDA will accept submitted comments on these fall guidance documents at any time, with one exception. Comments on the new Safer Technologies Program (STeP) are due Nov. 18, 2019.

Guidance on Safer Technologies Program

The FDA issued a draft guidance introducing its new Safer Technologies Program (STeP) for medical devices. The guidance describes SteP "as a new, voluntary program for certain medical devices and device-led combination products that are reasonably expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition associated with morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program; for example, this may include devices treating or diagnosing non-life-threatening or reasonably reversible conditions."

The draft guidance also identifies the eligibility criteria for the program. As a general criteria, the device must require marketing authorization via either the premarket approval, de novo, or 510(k) pathway. The specific criteria include devices that:

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1. should not be eligible for the Breakthrough Devices Program due to the less serious nature of the disease or condition
2. should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations that provide one or more of the following:

a. a reduction in the occurrence of a known serious adverse event
b. a reduction in the occurrence of a known device failure mode
c. a reduction in the occurrence of a known use-related hazard or use error
d. an improvement in the safety of another device or intervention

Guidance on 510(k) Submissions

The FDA also issued four final guidance documents related to 510(k) submissions:

1. The Special 510(k) Program guidance states that the focus of the program has changed from being "limited to review of changes that did not affect the device's intended use nor alter the device's fundamental scientific technology," to "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."
2. In the Abbreviated 510(k) Program guidance, the FDA states that it "believes that, within the … [p]rogram, the use of guidance documents may facilitate the review of 510(k)s through a reliance on 'summary reports' that briefly describe and summarize the testing performed to support the submission as recommended in relevant guidance document(s)."
3. The Format for Traditional and Abbreviated 510(k)s guidance lists the 20 sections and the prescribed order that should be included in each traditional or abbreviated 510(k) application, as well as a brief paragraph describing the preferred content for each section.
4. As its title suggests, the Refuse to Accept Policy for 510(k)s guidance "explain[s] the procedures and criteria FDA intends to use in assessing whether a … 510(k) submission meets a minimum threshold of acceptability and should be accepted for substantive review." The guidance includes checklists for traditional, abbreviated, and special 510(k) applications.

Guidance on De Novo Requests

Additionally, the FDA issued three final guidance documents related to de novo requests:

1. Similar to the Refuse to Accept Policy, the guidance on Acceptance Review for De Novo Classification Requests

"explain[s] the procedures and criteria [the] FDA intends to use in assessing whether a request for an evaluation of automatic class III designation (De Novo classification request or De Novo request) meets a minimum threshold of acceptability and should be accepted for substantive review" and includes relevant checklists.
2. The FDA and Industry Actions on De Novo Classification Requests: Effect on Review Clock and Goals guidance describes the different FDA actions that may be taken on de novo requests, the effect each action has on goals under MDUFA IV for de novo requests, and the different industry actions that may be taken on de novo requests.
3. The User Fees and Refunds for De Novo Classification Requests guidance addresses "(1) the types of de novo requests subject to user fees; (2) exceptions to user fees; and (3) the actions that may result in refunds of user fees that have been paid."

Guidance on Medical Device Software

Finally, on a single day in late September, the FDA released five final guidance documents related to medical devices and software:

1. Changes to Existing Medical Software Policies Resulting From Section 3060 of the 21st Century Cures Act – This guidance discusses the amendment to the definition of "medical device" by the 21st Century Cures Act to exclude certain types of software functionality.
2. General Wellness: Policy for Low Risk Devices – This guidance states that the FDA does not intend to examine low-risk products that simply promote a healthy lifestyle to determine if they are medical devices or, if they are medical devices, whether they comply with the premarket review and post-market regulatory requirements.
3. Policy for Device Software Functions and Medical Mobile Applications – This guidance is intended to inform manufacturers, distributors, and others about how the FDA intends to regulate (or not) select software applications intended for use on mobile platforms or on general-purpose computing platforms.
4. Off-the-Shelf Software Use in Medical Devices – This guidance addresses questions asked by medical device manufacturers regarding what they need to provide in a premarket submission to the FDA when they incorporate off-the shelf software into a medical device.
5. Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices – This guidance elaborates on the basic premise that software functions that are solely intended to transfer, store, convert formats, and display medical device data or medical imaging data are not medical devices subject to FDA regulations, unless the software function is intended to interpret or analyze clinical laboratory test or other device data, results,

or findings.

For more information, please contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler, chair of the firm's Food, Drug & Device group, at 317-231-7392 or lynn.tyler@btlaw.com.

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