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ALERTS

FDA Issues Final Guidance On Medical Device Safety And Performance-Based Pathway

January 29, 2019 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | New York | San Diego | South Bend | Washington, D.C.

The Food and Drug Administration (FDA) recently issued a final guidance document titled, “Safety and Performance Based Pathway” for medical devices. In this guidance, the FDA expands the Abbreviated 510(k) Program for demonstrating substantial equivalence by describing an optional pathway dubbed the Safety and Performance Based Pathway. The guidance states this pathway is for certain, well-understood device types, where a submitter would demonstrate that a new device meets FDA-identified performance criteria to demonstrate that the device is as safe and effective as a legally marketed device.

Criteria for Pathway

According to the guidance, the use of performance criteria is only appropriate when the FDA has determined 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 all the performance criteria.”

Implementation of Pathway

To implement the new pathway, the guidance states that the FDA plans to issue multiple future guidances, for each type of device deemed eligible, which will include the performance criteria and types of devices to which

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the criteria would apply. The information may include the relevant product code(s), appropriate intended uses, and appropriate indications for use. The FDA also intends to maintain a list of device types appropriate for the Safety and Performance Based Pathway on its 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.

To support an FDA finding of substantial equivalence under this program, the FDA expects a submitter to demonstrate that the new device meets the FDA-identified performance criteria by submitting a Declaration of Conformity to an FDA-recognized consensus standard, testing protocols, a summary of the data, and/or underlying data. When the performance criteria and testing methodologies are in an FDA-recognized standard (identified in the relevant FDA guidance) and the submitter uses the specified methods to establish that its new device meets the performance criteria, a Declaration of Conformity should be sufficient to support a finding of substantial equivalence. The guidance notes, however, that the FDA may request and review underlying data demonstrating that a new device meets the performance criteria and testing methodology.

Because of the shutdown, the final guidance has not yet been published in the Federal Register. Parties interested in submitting comments on the guidance should monitor the Federal Register for the deadline.

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.