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ALERTS

Food, Drug & Device Law Alert - FDA Releases Final Guidance On Evaluating Substantial Equivalence For 510(k)s

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The FDA recently issued a final guidance titled, “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications.” The draft guidance of the same name was issued in late 2011. Unlike the draft, the final guidance does not address Abbreviated or Special 510(k)s and states that those will be addressed in a separate document to be issued later.

The guidance states that its purposes are “to identify, explain, and clarify each of the critical decision points in the decision-making process FDA uses to determine substantial equivalence” and “to enhance the predictability, consistency, and transparency of the 510(k) program by describing in greater detail the regulatory framework, policies, and practices underlying FDA’s 510(k) review.”

Although the guidance “is not intended to implement significant policy changes to the current 510(k) review process,” it is nonetheless interesting. The guidance includes a flowchart summarizing the 510(k) review process “which has been updated to track section 513(i) of the FD&C Act and relevant regulations more closely.” The guidance also contains separate sections addressing the key points in the review process, including:

- the appropriate use of multiple predicate devices;
- the process related to determining whether a new device with new indications for use has a new intended use;
- the process related to determining whether different technological characteristics raise different questions of safety and effectiveness; and,
- when performance data, with special emphasis on clinical performance data, may be necessary to support a determination of substantial equivalence.

With respect to multiple predicates, the guidance states that the FDA will no longer accept reliance on “split predicates” in which a firm compares its proposed product to more than one previously-cleared device. FDA will allow a firm to use more than one cleared device to demonstrate substantial equivalence in some circumstances, such as "to show that FDA had found similar technology or indications to be substantially equivalent.” In this connection, the guidance introduces the concept of a “reference device,” defined as “[a] legally marketed device that is intended to provide scientific and/or technical information (e.g., test methodology)

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to help address the safety and effectiveness of a new technological characteristic."

The complete text of the guidance can be found here.

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