The FDA Expands the Abbreviated 510(k) Pathway (aka, the 'Safety and Performance Based Pathway')

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On January 22, FDA Commissioner Scott Gottlieb announced the FDA's latest steps to strengthen the FDA's 510(k) program for premarket review of medical devices.[1] As part of this initiative, the FDA finalized its framework for the Safety and Performance Based Pathway by finalizing a draft guidance formerly known as "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria."

The FDA's final guidance on the Safety and Performance Based Pathway sets forth a framework under which manufacturers of certain, well-understood device types may demonstrate substantial equivalence by showing that their proposed devices meet specific performance criteria, rather than by direct comparison with predicate devices. For eligible device types, FDA has indicated that the Safety and Performance Based Pathway, and use of performance criteria instead of direct comparison, is only appropriate when the FDA has determined that:

- The new device has indications for use and technological characteristics that do not raise different questions of safety and effectiveness than the identified predicate
- The performance criteria align with the performance of one or more legally marketed devices of the same type as the new device
- The new device meets all the performance criteria[2]

Before manufacturers can utilize the Safety and Performance Based Pathway, the FDA must first identify the device types to which such expansion of the Abbreviated 510(k) pathway will apply.[3] The FDA has established a new website that will, in the future, provide information about the types of devices to which the Safety and Performance Based Pathway will apply. At the time of publication of this article, in part due to delays caused by the recently-ended government shutdown, it is not clear when the FDA will begin to implement the pathway by identifying the first devices types and applicable performance criteria.

Finally, the FDA's recently finalized guidance also provides recommendations for submitters of Safety and Performance Based Pathway 510(k)s.[4] Manufacturers will want to ensure that each element recommended in the FDA's Refusal to Accept Policy for 510(k)s is included in the submission, and if a section is not applicable, that it is designated in the submission as not applicable. The FDA's recently finalized guidance also provides recommendations for specific sections of the submission.

[1] *See* FDA Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on latest steps to strengthen FDA's 510(k)

program for premarket review of medical devices.

[2] *See* Part II of the Final FDA Guidance for Industry and Food and Drug Administration, Safety and Performance Based Pathway, issued on February 1, 2019.

[3] *See id.*, Part III.A.

[4] *See id.*, Appendix.