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FDA RELEASES DRAFT GUIDANCE PROPOSING A SIGNIFICANT EXPANSION OF THE ABBREVIATED 510(K) PATHWAY FOR MEDICAL DEVICES

To Our Clients and Friends:

On April 12th, 2018, the Food and Drug Administration ("FDA") released draft guidance proposing a significant expansion of the abbreviated 510(k) pathway for medical devices that would allow applicants to rely on performance characteristics rather than direct comparisons to predicate devices ("Draft Guidance").[1] FDA plans to maintain a list of device types appropriate for the Expanded Abbreviated 510(k) program on the FDA website and to issue additional guidance on specific performance criteria.[2] Prior comments by FDA Commissioner Scott Gottlieb suggest that the new program could focus on device types with older predicate devices where direct testing has become challenging, and on "well-understood technologies like ultrasound imaging machines, common in vitro diagnostic devices, and blood pressure monitors."[3]

A 510(k) is a premarket submission to demonstrate that a proposed device for marketing is at least as safe and effective, that is, "substantially equivalent," to a "predicate device," which is a legally marketed device that is not subject to FDA's premarket approval ("PMA") requirements.[4] Under the Abbreviated 510(k) clearance pathway, applicants could use conformity to FDA-recognized consensus standards or FDA guidance to demonstrate *some* of the performance characteristics necessary to support a finding of substantial equivalence to a predicate device.[5]

The new Expanded Abbreviated 510(k) program would allow a submitter to use FDA guidance, FDA-recognized consensus standards, special controls, and other information to demonstrate *all* of the performance characteristics necessary to show substantial equivalence. FDA reasons that "[i]f a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets or exceeds those levels of performance for the same characteristics, FDA could find that the new device is as safe and effective as the legally marketed device."[6] In other words, direct head-to-head comparisons, including testing, against predicate devices would not be required to demonstrate substantial equivalence under the Expanded Abbreviated 510(k) program.[7] An applicant would be required to submit a declaration of conformity, a summary of the data, and/or the underlying data, depending on the performance criteria specified for the device at issue.

The Draft Guidance was foreshadowed by comments from Commissioner Gottlieb in an FDA Voice blog post in December 2017. In that post, Commissioner Gottlieb explained that, as a result of significant advances in technology, device manufacturers were increasingly encountering challenges when they tested new devices against older predicate devices, many of which had been marketed for decades. In light of this, the Commissioner announced that FDA would undertake steps to modernize 510(k) review, permitting increased flexibility and facilitating a streamlined process that could potentially accelerate

the rate at which new innovations are brought to market. In addition, the Commissioner noted that FDA's new guidance would be consistent with requirements under the 21st Century Cures Act to use the "least burdensome" means available to demonstrate substantial equivalence.[8]

FDA is accepting comments on the Draft Guidance until July 11, 2018.

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[1] FDA, Draft Guidance for Industry and FDA Staff: Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalent Through Performance Criteria (Apr. 12, 2018).

[2] FDA, Draft Guidance for Industry at 7.

[3] Commissioner Scott Gottlieb, *Advancing Policies to Promote Safe, Effective MedTech Innovation* (FDA Voice Blog, Dec. 11, 2017), https://blogs.fda.gov/fdavoice/index.php/2017/12/advancing-policies-to-promote-safe-effective-medtech-innovation/.

[4] 21 U.S.C. § 360c(i).

[5] FDA, Final Guidance: The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications (Mar. 20, 1998).

[6] FDA, Draft Guidance for Industry at 6.

[7] *Id.* at 7.

[8] Gottlieb, *Advancing Policies to Promote Safe, Effective MedTech Innovation*.

Gibson Dunn lawyers are available to assist in addressing any questions you may have regarding the issues discussed above. Please contact the Gibson Dunn lawyer with whom you usually work, any member of the Aerospace and Related Technologies industry group, or any of the following:

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