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Seeking to reduce premarket burdens, FDA proposes to expand Abbreviated 510(k) pathway for certain devices

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Building on recent efforts to streamline premarket review of medical devices, on April 12, 2018, the Food and Drug Administration (FDA) issued a draft guidance seeking to expand use of the historically underutilized Abbreviated 510(k) submission program, through which device sponsors may rely on guidance documents, special controls, and FDA-recognized consensus standards to demonstrate substantial equivalence. The proposed "Expanded Abbreviated 510(k) program" would provide an optional, streamlined premarket pathway for certain, well-understood medical device types through which device sponsors could demonstrate substantial equivalence using objective performance criteria, rather than head-to-head testing against a predicate device. The program is intended to provide a less burdensome approach to 510(k) clearance for certain device types and may result in faster premarket review times. However, specific device types to be included have not yet been announced, and the impact of the proposed program will ultimately depend on the types and number of devices that are deemed eligible.

While prior agency comments about the proposed pathway suggested a modernization of the existing 510(k) program, the draft guidance does not appear to represent a major shift in FDA policy. Under the proposed Expanded Abbreviated 510(k) program, sponsors of eligible devices would still need to demonstrate substantial equivalence to a claimed predicate device in terms of intended use and technological characteristics. However, where the technological characteristics of a new device differ from those of the predicate, the sponsor could show that the new device is as safe and effective as its predicate by demonstrating conformance to the objective performance criteria established by FDA in guidance, FDA-recognized consensus standards, and/or special controls. This is consistent with current pre-market expectations for certain devices, such as spinal fusion devices and endosseous dental implants, for which FDA typically does not require side-by-side testing to establish equivalence and, instead, performs an internal analysis to compare test results to predicates. For other devices where the test methods are similarly standardized, it is possible that FDA will perform similar internal analyses to establish acceptance criteria, although this is not described in the draft guidance. While this program will likely start with device types where side-by-side testing currently is not required, it lays the groundwork for expanding these expectations to other types of devices.

Implementation of the proposed Expanded Abbreviated 510(k) program would require additional FDA resources, including:

- **Establishing and maintaining a list of included device types.** FDA intends to establish and maintain a list of device types deemed appropriate for submission through the Expanded Abbreviated 510(k) program on its website. This list will be accompanied by guidance documents identifying the applicable performance criteria for each device type, recommended test methods, and other relevant information. It appears that FDA intends to rely on the experience and expertise of FDA staff, information in literature, and analyses of data on existing devices within a device type to establish these performance criteria, but the expected timelines associated with this work have not been announced. The speed at which FDA populates this list likely will depend on whether it will post acceptance criteria and recommended testing methods prior to publishing or finalizing guidance (as is currently done for *de novo* petitions), or whether it will wait for guidance publication or finalization. FDA reserves the right to update acceptance criteria or even remove devices from the list, which could occur if new information indicates that the performance criteria in the identified guidance do not fully support a substantial equivalence determination.

- **New Q-submission type?** The guidance recommends that sponsors seek feedback through the Q-Submission program if they are uncertain whether their device fits within an established Expanded Abbreviated 510(k) program. Although Q-Submissions for 510(k) notices currently exist, the draft guidance indicates that the agency should be able to make this decision without reviewing much of the information that typically would be expected to be provided in a Q-submission, leaving open the question of whether a separate—potentially streamlined—Q-submission process for these inquiries may be warranted.

The new program is intended to expand upon existing 510(k) pathways, not to replace them. Accordingly, the current Traditional 510(k), Special 510(k), and Abbreviated 510(k) pathways will remain available to applicants whose devices do not qualify for the Expanded Abbreviated 510(k) program, as well as for applicants whose devices do qualify, but who choose to use one of the other existing pathways instead.

FDA is currently accepting comments on the draft guidance. All comments must be submitted to the Federal Register under docket number FDA-2018-D-1387 by July 11, 2018.

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