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In the midst of government shutdown, FDA pushes ahead with 510(k) modernization

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Thirty-two days into the longest government shutdown in U.S. history, the Food and Drug Administration (FDA or the agency) announced two developments signaling further headway toward advancing its previously reported goal to modernize the 510(k) pathway: (1) issuance of a final guidance entitled "Safety and Performance Based Pathway," which finalizes the 12 April 2018 draft guidance entitled "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria"; and (2) solicitation of public comments on steps the agency can take to further enhance the safety of 510(k)-cleared devices.

Safety and Performance Based Pathway

When first announced, it was not clear how this pathway related to the existing Abbreviated 510(k) program. Despite the name change, however, the final guidance is virtually identical to the draft guidance that we analyzed last April on the Expanded Abbreviated 510(k) pathway with three notable differences, which are discussed below.

- **Third-party review.** The final guidance makes clear that device types previously eligible for third-party review that are now also eligible for the Safety and Performance Based Pathway will remain eligible for the 510(k) Third Party Review Program.
- **Inquiries regarding eligibility.** Sponsors are no longer advised to seek feedback through the Q-Submission program if they are uncertain whether their device is eligible for the program. For such situations, FDA now recommends seeking "feedback" from the appropriate office or division, without specifying the appropriate mechanism. It is unclear how such inquiries should be submitted, or how they will be managed by FDA, but the final guidance retains the proposition that these decisions typically could be made without the need to review underlying data, suggesting that informal inquiries may be possible.
- **Information and data requirements.** The final guidance includes a new high-level table outlining the types of information that may be required to support a new 510(k) notice through the Safety and Performance Based Pathway, which varies depending on the type of performance criteria and test methodology referenced in the submission. For example, if the submission relies on an FDA-recognized standard and the company's testing was performed in accordance with the methodology set forth in that standard, a declaration of conformity should be sufficient; however, if the submission relies on an FDA-established performance

criteria and deviates from FDA's specified test methodology (or where no methods are prescribed), the submission should include a summary of the company's data, the underlying test data, and the test protocol.

Like the draft guidance, the final guidance specifies that FDA intends to establish and maintain a list of device types deemed appropriate for submission through the Safety and Performance Based Pathway on its website, which will be accompanied by guidance documents identifying the applicable performance criteria and test methods recommended for each device type. To date, however, FDA has yet to release the promised list, or details about how that list will be created and updated, rendering the Safety and Performance Based Pathway unavailable to industry at present, despite issuance of the final guidance.

As previously reported, it still remains to be seen how FDA will develop these standards and whether failure to meet these standards for devices with a different benefit/risk profile will inherently push a device into the De Novo pathway or render them not substantially equivalent. Nevertheless, stakeholders are encouraged to submit suggestions of potential eligible products for which there are comprehensive FDA-recognized consensus standards, as well as evidence-based suggestions on what the performance criteria should be for specific device types. Suggestions can be submitted to docket number FDA-2018-D-1387 at http://www.regulations.gov.

It is unclear whether the Safety and Performance Based Pathway will offer any benefit to industry in terms of review times, or whether it will reinvigorate the use of alternative 510(k) pathways, which has declined over time. Only 61 Abbreviated 510(k)s were cleared by FDA in 2018; by comparison, 173 abbreviated 510(k)s were cleared in 2003, when the use of this mechanism was at its peak. Historically, there has been no advantage in review time for Abbreviated 510(k) notices compared to Traditional 510(k) notices. It is not clear whether the new Safety and Performance Based Pathway will reduce review times or meaningfully streamline the required elements of the 510(k) submission.

For now, the Safety and Performance Based Pathway 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 continue to be available. We note however, in its announcement on 26 November 2018, FDA stated that it would like this new Safety and Performance Based Pathway "to eventually supplant" the predicate-based 510(k) system. While such a change would require congressional authorization, FDA remains open to seeking such authorization, where required to further its agenda.

Reliance on predicates cleared more than 10 years ago

Tuesday's announcement also solicits public comment on steps that FDA can take "to further encourage medical device manufacturers to develop innovations that enhance the safety of 510(k) devices." FDA has specifically asked for comments to address the following questions.

- Should the FDA make public a list of devices, or manufacturers who market technologies, that rely on predicates that have been on the market for more than a certain number of years (e.g., 10 years)? If so, what would be an appropriate period of time?
- Should the FDA consider using other criteria to inform our point of reference?
- Are there other and/or alternative actions we should take to promote the development and marketing of safer, more effective 510(k) devices?

- Should the FDA consider certain actions that might require new authority, such as making at least some older devices ineligible as predicates?

As discussed in detail in our prior alert, the agency's current proposals imply that FDA would like to foreclose reliance on older device clearances as predicates and suggests that users should approach those technologies with some level of skepticism, which may not be warranted for many well-established technologies. However, these proposals also suggest FDA is willing to consider other approaches, and it is anticipated that FDA will face significant challenges from industry if it does seek an arbitrary and bright line "cutoff" of 10 years, for example.

Solicitation of public comments

Interested stakeholders can submit comments addressing the questions outlined above to docket FDA-2018-N-4751 at http://www.regulations.gov.

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