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FDA releases four final guidances on the 510(k) program; Special 510(k) guidance confirms new approach to eligibility and broader potential for IVDs

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On 13 September 2019 the U.S. Food and Drug Administration (FDA or the agency) published four final guidance documents on the 510(k) program:

- "The Special 510(k) Program."
- "Refuse to Accept Policy for 510(k)s."
- "The Abbreviated 510(k) Program."
- "Format for Traditional and Abbreviated 510(k)s."

FDA's March 1998 guidance entitled "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence" (New 510(k) Paradigm guidance) is now obsolete, entirely replaced by the final guidances on Special 510(k)s and Abbreviated 510(k)s.

The most significant changes appear to be to "The Special 510(k) Program," which replaces the 28 September 2018 draft guidance of the same name. Clarifying language in the Special 510(k) final guidance underscores the agency's shift in focus for what types of submissions are eligible for the program. Criteria for acceptance for review of changes to previously cleared devices through a Special 510(k) notice will focus on whether methods to evaluate the changes are well established and whether results can be sufficiently reviewed in a summary or risk analysis format. The final guidance also indicates that in the case of in vitro diagnostics (IVDs), the need for clinical data to evaluate changes will not necessarily be a bar to acceptance to the program.

The remainder of the guidances appear to have been released primarily to make conforming changes and do not represent major shifts in policy.

The Special 510(k) guidance

The Special 510(k) guidance is largely consistent with the draft Special 510(k) guidance, discussed in detail here. The final guidance retains the draft guidance's expansion of the Special 510(k)

program to allow review of certain changes to the indications for use of the device. Specifically, the final guidance clarifies that FDA's approach to Special 510(k) notices no longer emphasizes "changes that affect indications for use or alter fundamental scientific technology." Rather, in determining whether changes to an existing device can be reviewed through the Special 510(k) notice pathway versus a Traditional 510(k) notice, the agency will now focus on "whether the method(s) to evaluate the change(s) are well-established, and whether the results can be sufficiently reviewed in a summary or risk analysis format."

This approach is further established in a flowchart that instructs the reviewer to consider these two factors which, if affirmative, lead to the decision that the change is appropriate for review in a Special 510(k) submission. These are the more 'practical considerations' that FDA had always considered in assessing eligibility for the program, given its shorter initial 30-day review time, but they had not officially supplanted the prior considerations until now.

For IVDs, the final guidance carves out an exception to the practice of disqualifying for Special 510(k) consideration devices requiring clinical trial data for evaluating modifications, stating "...[t]he use of clinical specimens to conduct IVD verification and validation does not necessarily mean that a well-established method does not exist to evaluate the change." Moreover, compared to the draft, the final guidance includes five new examples of modifications involving IVDs which would be eligible for the program (and no examples which would be ineligible), suggesting expanded scope for using the Special 510(k) program for IVD changes, even those supported by clinical data.

The agency has also made clear that for certain devices – like point-of-care products that manufacture a biological product and certain reusable devices requiring reprocessing – modifications through a Special 510(k) generally would not be appropriate, due to a lack of well-established methods to evaluate such changes, or because the validation data would not be reviewable in summary or risk analysis format. It also clarifies that modifications that involve more than three disciplines (e.g., biocompatibility or electrical safety) generally would be ineligible (whereas the draft was not specific as to the number).

Additional guidances issued

Concurrent with the Special 510(k) final guidance, FDA released three additional guidances related to 510(k) submissions:

- "The Abbreviated 510(k) Program" guidance excerpts and updates language from the superseded the New 510(k) Paradigm guidance (1998), without major changes in policy. It appears to have been issued mainly to separate the Special 510(k) and Abbreviated 510(k) guidances into two separate documents, and retire the New 510(k) Paradigm guidance. Notably, it makes no mention of the "Safety and Performance Based Pathway" final guidance FDA released in February 2019, which the agency described as providing, "FDA's current thinking on expanding the concept of the Abbreviated 510(k) Pathway." This omission makes clear that these are two separate programs. For more on these modernizing trends, see our analysis of the "Safety and Performance Based Pathway" final guidance.

- Refuse to Accept (RTA) checklist: The "Refuse to Accept Policy for 510(k)s" guidance replaces the prior RTA policy guidance from February 2019 and updates the acceptance checklists for Traditional, Abbreviated, and Special 510(k) notices. In addition to the revised acceptance criteria for the Special 510(k) program discussed above, there are a few minor changes to the checklists for Traditional and Abbreviated 510(k)s. For example, there is a new section covering cybersecurity features, and there is greater specificity for test protocols and standards appropriate for assessing biocompatibility. FDA indicated it would not implement

the updated checklist for 60 days following its release in order to allow industry and the agency time to operationalize the associated updates to the 510(k) RTA guidance. During this grace period (until 13 November 2019), FDA will utilize the prior final RTA guidance to assess whether a 510(k) submission should be accepted for substantive review for Special 510(k) submissions as well as for all other submission types.

- "Format for Traditional and Abbreviated 510(k)s" replaces the guidance issued on 17 November 2005, updating internal cross-references and reflecting the agency's current preferences for 510(k) formatting.

Conclusion

With a focus on methods and risk analysis, these documents update FDA's approach to the 510(k) paradigm. The 510(k) final guidances follow a series of premarket review guidance documents released over the past two weeks that also address modernizing approaches to risk analysis methods. See our client alerts on the De Novo RTA checklist, Humanitarian Device Exemption Program, and the new benefit-risk decision tree for PMAs and De Novos.

On 31 October 2019 FDA will host a webinar on the Special 510(k) final guidance.

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