Medical Device Developments: FDA Finalizes Four 510(k) Guidance Documents

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In September, the U.S. Food and Drug Administration issued multiple final guidance documents related to the medical device program. In this Bulletin, we briefly address final guidances on the Special 510(k) Program, the Abbreviated 510(k) Program, the Format for Traditional and Abbreviated 510(k)s, and the Refuse to Accept Policy for 510(k)s.[1] These final guidance documents are part of FDA's ongoing efforts to streamline and improve the 510(k) program and device regulation more generally. Notable items include some changes in the Special 510(k) guidance from the draft to final versions, and the replacement of a previous (1998) guidance by the final Special 510(k) and Abbreviated 510(k) guidance.

While none of these guidances are legally binding for FDA or industry, they represent the agency's current thinking. Those in the medical device industry are well advised to review them. We provide a brief summary of the guidances and note the larger context of recent FDA device guidance below. We will not describe the 510(k) regulatory pathway in this Bulletin.[2]

Overview

Special 510(k) Program Guidance

The Special 510(k) final guidance replaces draft guidance on the Special 510(k) program that was issued in September 2018. This Program provides an optional pathway for qualifying medical device modifications in which a manufacturer modifies its own legally marketed device. In addition to replacing the 2018 draft guidance, the Special 510(k) final guidance, together with the final guidance on the Abbreviated 510(k) Program, supersede and replace FDA's previous (1998) guidance on expanded 510(k) programs (The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence).

Among other things, the guidance discusses the types of device submissions that are eligible for the Special 510(k) Program, related criteria for acceptance, and the format of a Special 510(k) submission. The guidance maintains much of the current thinking described in the 2018 draft guidance of the same name.[3] However, there is an increased emphasis on having well-established

1 See FDA, *Guidance for Industry and Food and Drug Administration Staff, Special 510(k) Program* (Sept. 2019), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program FDA, *Guidance for Industry and Food and Drug Administration Staff*, Abbreviated 510(k) Program (Sept. 2019), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program FDA, *Guidance for Industry and Food and Drug Administration Staff, Format for Traditional and Abbreviated 510(k)s* (Sept. 2019), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks and FDA, *Guidance for Industry and Food and Drug Administration Staff, Refuse to Accept Policy for 510(k)s* (Sept. 2019), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks, respectively.

2 For an agency overview of the 510(k) pathway, see, "Premarket Notification 510(k)," available at https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k. More general medical device information is available at, "Device Advice: Comprehensive Regulatory Assistance," https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance.

3 See A. Minsk, S. Ray, and G. Razick, *FDA Launches Pilot to Expand the Special 510(k) Program*, Arnall Golden Gregory FDA Bulletin (Oct. 2018), available at https://www.agg.com/FDA-Launches-Pilot-to-Expand-the-Special-510k-Program-10-23-2018, for a more detailed discussion of the expansion of the Special 510(k) program and related 2018 draft guidance.

evaluation methods and ensuring that the evaluation methods will yield results that may be sufficient for review in a summary or risk analysis format. Also, there is a clarifying change in relation to in vitro diagnostics (IVDs). The final guidance indicates that clinical data may not necessarily be required in all cases in order to evaluate proposed changes (e.g., the guidance notes that, "[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"). The guidance also offers a flowchart and list of recommended content, as well as a list of submissions that are not appropriate for the Special 510(k) Program for various reasons (e.g., a submission in which evaluation of the change would involve more than three scientific disciplines or situations in which a recent inspections has found violations related to design control of the 510(k) device).

Abbreviated 510(k) Program Guidance

The Abbreviated 510(k) Program allows submitters and agency reviewers to reference and use appropriate FDA guidance documents, special controls, or voluntary consensus standards (some or all) to facilitate the agency's review of 510(k) submissions. The new final document guidance does not introduce major changes in policy from the now superseded 1998 guidance (see above), although it includes some updates. We recommend that companies planning to pursue the Abbreviated 510(k) Program consult this new final guidance.

Format for Traditional and Abbreviated 510(k)s

This final formatting guidance replaces a previous guidance document on the format of 510(k) submissions (issued in 2005). The guidance lays out in detail FDA's current thinking on the proper format for Traditional and Abbreviated 510(k) notifications (it does not address Special 510(k) submissions or other types of device submissions, such as a Premarket Approval Application). Companies should consult this guidance during the preparation of Traditional and Abbreviated 510(k)s to ensure that their submissions are in the agency-preferred format. Among other things, having 510(k)s follow a consistent format assists agency reviewers in conducting a more rapid, comprehensive, and complete evaluation of the submission. For companies, following the guidance can prevent a situation in which the agency refuses to accept a submission (see below).

Refuse to Accept Policy for 510(k)s

The purpose of the guidance on FDA's Refuse to Accept Policy is to provide notice of the threshold requirements for FDA to accept a 510(k) submission for review. This ensures that the submission is sufficiently complete to allow review, and avoids wasted time and resources on both the agency and industry side. This final guidance replaces previous guidance issued earlier this year. It also updates the acceptance checklists used by FDA staff to determine whether a submission meets the minimum requirements to be accepted for review. The guidance includes updates to the checklists for Traditional 510(k)s, Special 510(k)s, and Abbreviated 510(k)s. Updates include items such as a section addressing cybersecurity and additional information regarding test protocols. FDA indicated that the new checklists will begin use on November 13, 2019.

AGG Observations

- The Special 510(k) Guidance, while not radically different from the draft guidance, does have some clarifying changes in relation to the submission types that are and are not eligible for the program, review criteria, and a change in the guidance approach to clinical data and IVDs.
    - The other three final guidance documents do not appear to reflect significant changes in current agency thinking as compared to previous guidances that are being finalized or replaced.
    - We recommend that companies consult these final guidance documents as they move through medical device development and determine available and appropriate pathways for 510(k) submissions.

- FDA has released numerous medical device-related guidance documents this year (see, e.g., AGG's recent article on new De Novo guidance).[4] Device companies should be sure to stay updated on new guidances periodically in order to ensure that they are referring to the most recent guidance.

4 A. Minsk and G. Razick, *FDA Releases Guidance on Acceptance Review for De Novo Classification Requests*, Arnall Golden Gregory Client Alert (Sept. 2019), available at https://www.agg.com/FDA-Releases-Guidance-on-Acceptance-Review-for-De-Novo-Classification-Requests-09-25-2019.

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