Morgan Lewis

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Medical Device Update: FDA Issues Draft Guidance on Streamlined De Novo Classification Process

On August 14, the Food and Drug Administration (FDA) issued a draft guidance titled "*De Novo* Classification Process (Evaluation of Automatic Class III Designation)."[1] The draft provides guidance on a streamlined process for submitting requests to the FDA to down-classify certain low-to-moderate-risk devices that have been automatically classified as Class III. The de novo process is an important premarket pathway option for companies that intend to market novel device technologies that the FDA has not previously reviewed or classified, such as novel health IT or laboratory diagnostic technologies.

The FDA issued the draft guidance to include changes made by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) to the "de novo" classification provision of the Federal Food, Drug, and Cosmetic Act (FFDCA). Most notably, FDASIA eliminated the requirement for applicants to first file a 510(k) submission prior to seeking de novo down-classification—a step that added considerable time and delay to the de novo process. The new draft guidance reflects the elimination of the 510(k) requirement and also provides recommendations on the information to include in a de novo submission. Significantly, the draft guidance indicates that the FDA will expect de novo submissions to include detailed information on the manufacturer's (presumably unsuccessful) search for a predicate device.

Background

Under the FFDCA, a novel device that has not been previously classified by the FDA, and for which there is no legally marketed predicate device, will be automatically classified into Class III.[2] Section 513(f)(2) of the FFDCA permits manufacturers of low-to-moderate-risk devices that are automatically classified as Class III to submit a de novo petition to the FDA to seek reclassification of such devices. This process is intended to allow companies with novel, but lower risk, device technologies to avoid filing a premarket approval application (PMA), the most burdensome type of premarket submission for a medical device.

Prior to the enactment of FDASIA, manufacturers were required to first submit a 510(k) notification before submitting a de novo petition. This two-step process, however, proved onerous for both applicants and the FDA, resulting in lengthy review times for de novo submissions. In some cases, de novo review times exceeded the average review time for a PMA, rendering the de novo process a nearly unworkable option for companies with novel low-to-moderate-risk devices. In response to criticism and industry pressure to streamline de novo down-classification, Congress modified the FFDCA under FDASIA to permit manufacturers to submit a de novo petition without a preceding 510(k) submission. The August 14 draft guidance outlines this more direct process for submitting a de novo application and sets forth the required content of the application.

De Novo Criteria

The draft guidance clarifies that the FDA will consider requests for de novo classification only if the following criteria are met:

- There is no identifiable predicate device.
- The device is of low to moderate risk, and general controls or general and special controls would provide reasonable assurance of the device's safety and effectiveness.

1. View the draft guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM273903.pdf.

2. Section 513(f)(1) of the FFDCA, 21 U.S.C. § 360c(f)(1).

- The known risks and benefits of the device can be explained, the known risks can be effectively mitigated, and the device's effectiveness can be assured through application of general controls or general and special controls.

De Novo Process

The draft guidance includes a discussion of the de novo process as well as a flow chart of the process at Attachment 1. As a first step, manufacturers will have the option to obtain early feedback from the FDA on the suitability of a device for de novo classification by requesting a presubmission review. Alternatively, manufacturers may simply submit a de novo application without obtaining this early feedback. Upon receipt of a de novo submission, the FDA will verify that another submission for the same device is not under review, will check to ensure that all required content is provided, and will conduct a classification review of legally marketed device types to determine whether an existing legally marketed device of the same type exists.

Assuming that the submission passes this initial review, the FDA will conduct a substantive review. If the FDA determines that additional information and/or data is necessary to determine whether general controls or general and/or special controls can provide reasonable assurance of safety and effectiveness, it may issue an additional information (AI) letter. Once the FDA determines that the data and information demonstrate that the device meets the criteria for de novo classification, it will issue an order granting the request for de novo classification and specifying the classification of the device into Class I or Class II and whether the device is exempt from premarket notification requirements.

The FFDCA requires that the FDA make a classification determination for the device by written order within 120 days of the de novo request.

Content of a De Novo Submission

The FDA outlined the recommended content of a de novo request in Attachment 2 of the draft guidance. In addition to certain administrative information and supporting data, the draft guidance requests that de novo submissions include detailed information on the search for a legally marketed device of the same type (i.e., a predicate device). Specifically, the guidance states that submissions should not only include a list of regulations, approved PMAs, and/or product codes that may potentially be similar to the subject device, but they also should include a rationale for why the subject device is different from and/or does not fit within any identified regulation, PMAs, and/or product codes. Additionally, for devices proposed to be reclassified as Class II, the submission must include proposed special controls along with cross-references to other information within the submission that demonstrate that the device meets those special controls. Accordingly, manufacturers may need to determine the content of a new guidance document for special controls when preparing their de novo submission. Finally, the submission must list each risk, identify the reason for each risk, and identify a proposed mitigation for each risk.

Contacts

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