Tips for a Successful FDA Medical Device Submission

Client Alert
2.23.2023

In order to secure approval of a medical device, a sponsor must use one of several pathways prescribed by the FDA. The primary avenues are: (i) the 510(k) Pre-Market Notification ("PMN" or "510 (k)") clearance, pursuant to Section 510(k) of the Food, Drug and Cosmetic Act ("FDCA"); (ii) the Pre-Market Approval ("PMA"); and (ii) the de novo submission. This Alert will focus on the most common pathway, the 510(k). Virtually all Class II medical devices are cleared via the 510(k) submission process, which involves devices that are "equivalent" to a device already placed into one of the three classification categories. While the 510(k) process is the least complicated, sponsors sometimes find it obscure and difficult to navigate. We will explore the most effective strategies for securing a 510(k) clearance, with a focus on the needs of smaller companies that have less experience with this pathway. In a future alert, we will focus on the de novo approval process, for novel products for which no equivalent device exists.

The first step is to ensure that the sponsor possesses the requisite supporting data. Many companies rush headlong into the application process only to find that they lack sufficient scientific support for their concept. An applicant should determine as soon as possible what advance work is needed. Working with a lawyer or consultant will facilitate the determination of what the FDA is likely to want. Sponsors should analyze the summaries of competitors' approvals and review the dozens of FDA guidance documents available on the agency's website. In general, the categories of data the FDA may require include bench testing, clinical trials, usability analysis and where appropriate, software validation.

The next step is to choose a predicate. A predicate device is a medical device that is similar in form and function (substantially equivalent) to the sponsor's product. It is used as a point of

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reference for the new 510(k) submission. The choice of a predicate device is critical. It will determine in large measure whether the application is successful. The predicate's device code and regulation number will help determine indications for use. The design and performance of the device will inform the decision regarding whether the device performs as well (or better) than the predicate. Sponsors will need to know the characteristics of the predicate device, appropriate specifications and the science needed to demonstrate equivalence. This is a complex undertaking, and it should begin as soon as possible.

Once these steps are completed, the sponsor should seriously consider requesting that the FDA grant a pre-submission meeting. A pre-submission meeting is designed to allow sponsors the opportunity to ask the review team any questions they have before the submission is presented. These meetings are very useful, in that they provide an opportunity to receive valuable input on the predicate choice and required data. The process involves a detailed written request to the FDA for the meeting. This should contain as much information as possible, including draft testing protocols and testing summaries. The FDA will respond with comments just before the meeting. It is incumbent upon the sponsor to address the FDA's comments and concerns at the meeting to ensure that the dialogue is productive. The review team will help provide a roadmap for the submission if the sponsor asks the right questions. In addition, the agency will often open a line of communication to the sponsor to assist in follow-up actions. It is strongly recommended that the applicant avail itself of the services of a professional to assist in preparation for the meeting.

Another important consideration is determining who should attend the meeting. The FDA will usually have a large contingent of specialists, most of whom will be on the review team. The sponsor should resist the urge to bring too many people. The attendees should comprise a senior executive, a lawyer or consultant who will have ongoing involvement in the process and several technical or scientific experts who can answer complex questions about the device. Make sure to follow up with the review team after the meeting. The agency will request minutes from the sponsor, so at least one attendee should take comprehensive notes during the meeting. This is also the time to open that all important dialogue (both phone and e-mail) with the review team.

Once the pre-submission process is complete, the 510(k) preparation begins. The feedback from the pre-submission meeting is critical to the success of the application. A comprehensive analysis of required testing and a clear and comprehensive Device History File are important parts of this process. The sponsor should begin to work on developing labeling and identifying any claims it wishes to make for the product. Errors in labeling and claim development are a major reason the FDA refuses to accept submissions.

Generally, 510(k) applicants can expect acceptance review decisions within 15 calendar days; substantive review decisions within 60 days; and final decisions within 90 days. Applicants with outstanding review issues will be notified within 100 days. (In our experience, COVID has extended these timelines, sometimes by months). This is an ongoing process, requiring considerable back and forth with the FDA. Each time the agency requests more information, the submission is paused pending the response from the sponsor. A sponsor can and should ask for further clarification in the

event a question is not clear.

It is important that applicants remain patient. The process almost always involves unpredictable twists and turns that can delay the review. Sponsors can facilitate matters by listening to the FDA and ensuring that they have assembled all the information the review team needs. Again, this may seem like common sense, but many companies try to rush the process by assuming they can augment the submission later. First impressions are critical – make sure you put your best foot forward at the outset.

A successful completion of a 510(k) submission is a gratifying experience. Of greater long-term importance is the goodwill established with the FDA. Reviewers are human and they draw conclusions based on their first encounters with sponsors. A good start with the first application helps ensure many other successful future clearances.

If you have any questions or would like more about the 510(k) clearance pathway, please contact your Butzel attorney, or the author of this alert.

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