This information should not be considered to represent advice or guidance on behalf of the U.S. Department of Health and Human Services or any agency or office thereof.

510(k) Pre-Submission Meetings

Context

Before submitting a Premarket Notification (510(k)), medical device innovators may meet with the U.S. Food and Drug Administration (FDA) to ask questions and obtain feedback on their proposed device development plans. You may obtain FDA's feedback about your device and ask specific questions about the regulatory process by formally submitting a pre-submission meeting request.

The 510(k) is the most widely used type of marketing application for medical devices. The FDA Center for Devices and Radiological Health (CDRH) reviews 510(k)s based on a wide range of submitted documentation including the technical description of the device and its intended use. This regulatory pathway is primarily for Class II devices (i.e., known devices that are considered to have moderate risk). What is unique about the 510(k) submission process is that, rather than independently demonstrating the safety and effectiveness of a new device, a technical and/or clinical comparison is made to a similar device that is already cleared for the market.

The existing marketed device is known as a predicate device, and the comparison of a new device to a predicate is the basis for claiming substantial equivalence (SE), which enables marketing authorization of the new device. SE is demonstrated by showing that the new device and the predicate device have both:

1. The same "intended use" (i.e., the same general purpose of the device or its function)
2. Either the same technological characteristics, or the differences in technological characteristics do not raise different questions of safety and effectiveness

It is also important to review and compare the indications for use (IFU) between the new device and predicate device. While the intended use describes what the device does, the IFU describes how, when, where, and under what conditions the device is used.

How to Prepare

Know the 510(k) Process

Start by searching FDA's publicly available 510(k) database to identify one or more potential predicate devices. The 510(k) summaries found in the database can include the IFU statements, device descriptions and performance testing utilized by predicate devices.

If there are several potential predicates, innovators can discuss the options with FDA in the pre-submission meeting. Generally, selecting a single predicate device simplifies and facilitates the decision-making process. If a suitable predicate device cannot be identified, investigate using the De Novo or Premarket Approval (PMA) pathways instead.

Recognize that a 510(k) submission is not a grant or patent application—the novelty of the device is not the focus of the review process. Rather, for the device to meet the requirements of the 510(k) process, it must be as safe and effective as the chosen predicate device.

Figure 1 is the SE flow chart used by CDRH staff. You can use it to help determine if a given predicate device may be an appropriate basis for a 510(k) application:

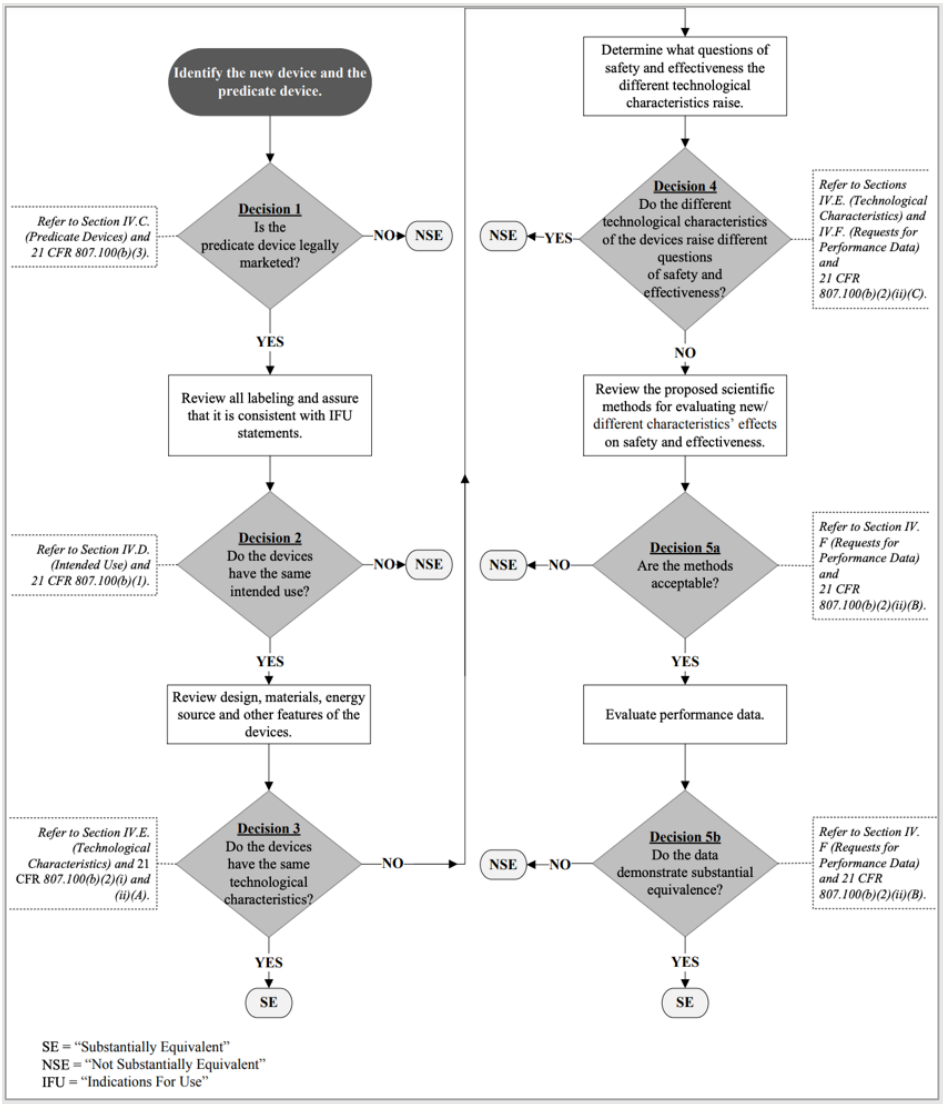

Figure 1. Snapshot of the 510(k) Flowchart

From the flowchart, it is important to understand the key decisions needed for SE determination. Decision 2 is a critical step: review the publicly available 510(k) documents for the proposed predicate device to ensure that the new device has the same intended use as the predicate. Afterward, since the new device is rarely 100% identical in form/design/materials, the result of Decision 3 is typically "no" (which is acceptable). From there, the submission must support, with scientific and/or clinical evidence, that the differences in technological characteristics do not raise different questions of safety and effectiveness compared to the predicate device (Decision 4) in order to successfully navigate to review of performance data (Decision 5).

Technical Data and Information

The request for a pre-submission meeting starts with a documentation package that should include:

- A summary of the device, including what it is and does
  - A description of the technological characteristics of the device
- An IFU statement of the device
- A detailed comparison of the device and the proposed predicate device
- A detailed plan of how the safety and efficacy of the device will be validated

Please note that the above list of items to include is not exhaustive, and details may vary depending on what you are proposing in your pre-submission (see the Q-submission guidance document in the Resources section below).

It is important to include specific questions in the pre-submission that address the proposed validation plan and an explicitly proposed predicate device. FDA staff will not design a validation plan or identify a predicate device for you but will provide feedback on plans included in the pre-submission meeting package.

Regulatory Resources

- Guidance documents
  - The 510(k) Program – describes current review practices for premarket notification submissions
  - Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (see Appendix 1 for pre-submission acceptance checklist)
  - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals
- Public FDA databases
  - The 510(k) Premarket Notification Database
    - Tip: Read premarket notifications to learn about clinical and non-clinical testing overviews, IFU statements, and relevant standards utilized by potential predicates. These topics are summarized (as applicable) within the 510(k) summaries posted in the database; the actual 510(k) submissions are not public.
  - De Novo Database

        - The De Novo database is also a resource for identifying potential predicate devices because once a De Novo is granted, it becomes a valid predicate for the 510(k) process.
    - Product Classification Database
- FDA webpages
    - Premarket Notification 510(k)
    - CDRH Learn
- NIH network
    - Work with program officers and obtain regulatory feedback within NIH
    - Coordinate a meeting with the NIH Small Business Education and Entrepreneurial Development (SEED) Innovator Support Team
- Direct links to NIH SEED resources on related topics
    - Written communication
- Submission mechanisms
    - CDRH information page on medical device submissions (eSTAR). This is a recently updated process so obtain the most up to date information from FDA.

What to Expect

Timeline

FDA intends to provide written feedback on pre-submission meeting requests within 70 days of receiving your meeting request, or five days prior to the scheduled meeting, whichever is sooner. Along with the pre-submission, you should provide FDA with three or more proposed dates, generally between 60 and 75 days after submission, to hold the pre-submission meeting. FDA may reach out to find a mutually agreeable date if none of the three proposed dates are possible.

For the actual 510(k) submission, FDA aims to complete review within 90 days. There is a 15-day screening period to assess whether the submission contains the appropriate information to begin a substantive review. Once accepted for substantive review, FDA may send requests for additional information, either interactively or in a hold letter. If a letter is issued, it is generally done by day 60 and pauses the FDA review clock. You will have 180 days to fully respond to any deficiencies outlined in the letter. After you respond to the request for additional information, the review clock resumes. Once FDA has received your complete response, they intend to engage in an interactive review process (e.g., via email) until a decision is communicated.

Pre-Submission Meeting with FDA

Meetings are generally limited to a one-hour timeframe. This is not the time to “pitch” the device to FDA. Instead, it is recommended that you use this time to focus on clarifying FDA’s feedback to get the information needed to prepare for your upcoming 510(k) submission.

Plan for an all-hands-on-deck situation in the days prior to the pre-submission meeting. The time between receiving feedback from FDA and the meeting date is short, so tailoring the discussion to clearly understanding FDA's feedback is the most valuable use of the meeting time. In addition, you can hold one or more dry runs (contact your program officer or the NIH SEED for assistance) to ensure timing and messaging are being carefully managed. It is important to understand that, although you may have made progress on your device since submitting the meeting request, FDA will only provide feedback on the information you submitted when you requested the meeting.

It is your responsibility to take notes and submit meeting minutes, along with any presentation materials, to FDA for review within 15 days of the meeting. These minutes will be added as an amendment to the submission.

Plan for Meeting Outcomes and Next Steps

You should reference FDA's feedback, and the minutes from the pre-submission meeting, when preparing your 510(k) submission. It is recommended to include a summary of how the feedback was addressed in the 510(k) and include the Q-submission number.

If, prior to sending in your 510(k) submission, you believe additional feedback from FDA is needed, then a supplement to the pre-submission may be submitted. A pre-submission supplement is a new request for feedback and/or a meeting about the same device and indications for use and has the same review timelines as the pre-submission.

General Tips

- A good time to obtain feedback from FDA is when the device is near its final design, has a well-documented plan of study in place, and details of validation data intended to support a 510(k) submission are ready. It is important to seek feedback from FDA at a time when it will be of most value.
    - Initiating a pre-submission meeting early might mean that you still have several open questions related to the design of your device or study. Under these circumstances, FDA may not be able to provide as valuable feedback as when finalized designs and plans are provided.
    - Submitting a 510(k) pre-submission meeting request too late may mean you have spent time and money collecting data that FDA views as insufficient to support a marketing application.
- FDA will not identify a potentially applicable predicate, plan a study, or write an IFU statement for you. However, reviewers will generally provide feedback on the acceptability of a proposed predicate, initial study plan, IFU statement, or proposed regulatory pathway. All written questions should refer to content provided in the documentation package accompanying the pre-submission meeting request.

- Use the pre-submission meeting to address any confusion or lingering questions based on the FDA's written feedback. Re-presenting information already provided in the pre-submission is

not advisable. Also, FDA will not provide feedback on any new data presented during the meeting.

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