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.

Breakthrough Device Designation Requests

Context

With the goal of providing patients and healthcare providers timely access to medical devices with the potential to provide more effective treatment or diagnostic options for seriously ill patients, the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) established the Breakthrough Devices Program. Breakthrough device developers benefit from accelerated interactions with the review team, leading to faster identification (and hopefully resolution) of FDA's concerns during the premarket review process. Additionally, this program enables FDA to prioritize the review of marketing submissions (e.g., premarket approval (PMA), premarket notification (510(k)), or De Novo classification request) of designated Breakthrough Devices. The program is available for devices that may provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

A few things to consider and know about the Breakthrough Devices Program:

- The program does not lower the bar for safety or benefit, and the time to develop the technology *prior to submission of a marketing application to FDA*, is not directly impacted by the designation.
- A Breakthrough Device Designation (BDD) request is a stand-alone request to FDA; it cannot be combined with any other requests such as a pre-submission meeting.
- FDA will issue a grant or denial decision for each BDD request within 60 calendar days of receipt. In general, FDA intends to interact with the submitter within 30 days regarding any requests for additional information needed to inform the designation decision.

One potential business benefit of receiving a BDD is the ability to leverage FDA's acknowledgement of the significant innovation or unmet need to increase appeal to potential investors and partners, and possibly reach more patients. However, it is up to the innovator to capitalize on such an opportunity; this does not factor into FDA's review of the technology.

Key Takeaways

- FDA commits more resources to review breakthrough devices on an accelerated timeline. The premarket process for a designated breakthrough device is also more interactive than for non-designated devices.
- Although there is no formal change in timeline of the premarket submission (e.g., PMA, 510(k), De Novo), and the overall amount of data required by FDA is not different from what is required for the same device without a BDD, faster feedback and guidance from FDA may provide efficiency to the device development, assessment, and review – and help accelerate overall time to market.
- To obtain a BDD, you must justify how the device meets specific breakthrough criteria. You must also demonstrate that the device's development is sufficiently mature to meet the performance demands (i.e., it is more than a prototype or concept).

To participate in the program, submit a package of documentation to CDRH called a "Breakthrough Device Designation Request."

How to Prepare

Technical Data and Information

To obtain a BDD, you submit a data package demonstrating that the new technology meets **two** qualifying criteria:

BDD First Criterion: The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

BDD Second Criterion: The device also meets at least one of the following:

a. Represents breakthrough technology

   From the FDA guidance document:

   FDA considers whether the device represents a novel technology or novel application of an existing technology that has the potential to lead to a clinical improvement in the diagnosis, treatment (including monitoring of treatment), cure, mitigation, or prevention of the life-threatening or irreversibly debilitating disease or condition.

b. No approved or cleared alternatives exist

c. Offers significant advantages over existing approved or cleared alternatives

d. Device availability is in the best interest of patients

Innovators can leverage published articles, preliminary studies, design documents, or other forms of data to support that the two criteria are met. The BDD request must also include a detailed description of the device and clear statements of its intended use (what it does) and indications for use (how, when, where, under what conditions, and by whom will it be used).

FDA uses the submitted data package to decide if there is a "reasonable expectation" that the device will meet the criteria. As described in the FDA's Breakthrough Devices Program guidance document,

> *Because decisions on requests for designation will be made prior to marketing authorization of a device, for the purposes of designation, FDA believes it is appropriate to consider whether there is a reasonable expectation that a device could provide for more effective treatment or*

diagnosis relative to the current standard of care (SOC) in the U.S. A complete set of clinical data is not required for designation. Instead, a sponsor should demonstrate a reasonable expectation that the device could provide for more effective treatment or diagnosis of the disease or condition identified in the proposed indications for use.
This includes a reasonable expectation that the device could function as intended (technical success) and that a functioning device could more effectively treat or diagnose the identified disease or condition (clinical success). Mechanisms for demonstrating a reasonable expectation of technical and clinical success could include literature or preliminary data (bench, animal, or clinical). For example, a sponsor might provide preliminary bench data to support the potential for technical success and literature to support that a given principle of operation could more effectively treat or diagnose the identified disease or condition.

Even if the design of the device clearly satisfies the criteria, FDA may decline the request if data demonstrating the device's ability to achieve its proposed performance characteristics are not included. Testing does not need to be complete, but sufficient data describing the capabilities of the device should be included to support the BDD request.
Appendix 1 of the FDA guidance document on the Breakthrough Devices Program includes an illustrative outline of the content and information to include in the request.

Regulatory Resources

- Breakthrough Devices Program – overview of the Breakthrough Devices Program's procedures and policies
    - Based on Section 515B(b) of the FD&C Act)
- Guidance documents
    - Breakthrough Devices Program – guidance document describing program and policies in detail
    - Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program – the Breakthrough Devices Program utilizes the same submission pathway as other Q-submissions (such as study risk determinations and other CDRH interaction mechanisms)
- Public FDA databases
    - Product Classification – access to regulatory information on medical devices such as product descriptions, codes, and responsible CDRH review offices
        - Tip: Include information on related product codes and regulations in the background information section of the BDD request; discuss whether these are applicable to the breakthrough device
    - PMA, De Novo, 510(k) – access to information on market authorized medical devices
        - Tip: Read and review summaries for clinical and nonclinical testing overviews, indications for use statements, and relevant standards accepted by FDA for similar devices

- NIH network
    - Work with program officers to obtain feedback within NIH
    - NIH awardees can request a meeting with the NIH Small Business Education and Entrepreneurial Development (SEED) Innovator Support Team to ask questions about this process and request that the team review the draft cover letter and overall approach. However, the SEED office does not review or comment on the scientific validity or data elements of the submission.
- Submission mechanisms
    - CDRH information page on medical device submissions (eCopy, eSTAR). This is a recently updated process to obtain the most up to date information from FDA.

Presentation

When seeking a BDD, you will compile the paperwork, device descriptions, and justifications into a PDF and submit this data package to FDA. The document should be as concise as possible, while providing evidence the two criteria are met, including that the product is sufficiently mature in design and validation. It is also important to demonstrate that formal premarket review is planned for the near future. You should indicate which marketing application type (PMA, 510(k), or De Novo request) you intend to submit and include a rationale for this approach in support of your Breakthrough Device designation request.

Appendix 1 of the guidance document on the Breakthrough Devices Program includes an outline and expected format for the request.

Submission Process

Documents are submitted through CDRH's most current processes. The package should contain a cover letter specifying the intent of a Breakthrough Device Designation Request and the required supporting documents. There is no fee to submit the request.

What to Expect

Timeline

FDA intends to make a decision within 60 days of receipt of a BDD request.

Format of Interaction

In general, FDA intends to interact with the submitter via email within 30 days after the designation request has been submitted regarding any requests for additional information needed to inform the designation decision. FDA sends a decision letter either granting or denying the BDD. In cases where it is denied, FDA provides justification for its decision—its rationale may be beneficial for further development of the product. Typically, there is no meeting to discuss FDA's decision or these materials; however, a separate pre-submission request may be submitted to FDA to request a meeting for additional clarification. Additionally, follow-up questions may be sent to the lead reviewer noted in the decision letter.

The subsequent interactive review that a Breakthrough Designated Device undergoes is intended to be expedited through increased priority and attention from the FDA review staff. For example, rather than placing their evaluation on hold and drafting a formal letter to resolve minor deficiencies, the reviewers are more likely to reach out directly via phone or email, as soon as questions come up.
It is ideal to precede a BDD request with a pre-submission meeting to address any major questions related to the device, its intended use, and its expected regulatory path. Whether or not the BDD is granted, you may schedule subsequent pre-submission meetings before the eventual marketing submission. If a Breakthrough Device designation request is denied, a new request may be submitted with additional information addressing the deficiencies outlined in the denial letter.

General Tips

- Recognize that, while BDD will streamline later regulatory reviews, preparation for a BDD request takes time and effort. Depending on the size and resources of your team, creating these documents with sufficient quality to participate in these programs may unintentionally *extend* the total time to market (especially when the designation decision is uncertain).
- BDD requests are not an opportunity to ask questions of FDA, nor are they an ideal mechanism for receiving FDA feedback.
- It is a best practice to get questions about intended use and data requirements answered before submitting a BDD request. For regulatory questions early (or late) in device development, request feedback through a CDRH pre-submission meeting.
- One of the primary benefits of the program is clearly specified by CDRH: “to efficiently address topics as they arise during the premarket review phase.” For some innovators, this helps them address the complexities of the new technologies. Note that the standard premarket processes remain the same (PMA, De Novo, and 510(k)), and there is no specific change to the committed review timeline for premarket applications, though Q-submission requests are expedited.
- There is a potential benefit of BDD that is not directly tied to FDA processes. A BDD from FDA may increase investor interest or enhance the success of patient/provider outreach.

Last updated September 2023