Breakthrough Devices Program

Clinical Chemistry and Clinical Toxicology Devices Panel Meeting

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Learning Objectives

- Provide an overview of the Breakthrough Devices Program
- Review the criteria for Breakthrough Device designation
- Describe program features

Breakthrough Devices Program

- Intended to provide patients and health care providers with timely access to devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
- Expedites the development, assessment, and review of certain devices that meet the program eligibility criteria

Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

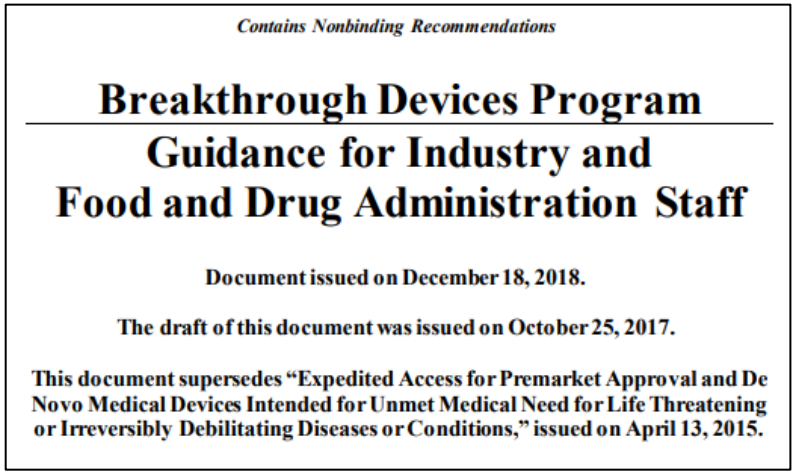
Principles & Benefits

- Interactive and timely communication
- Prioritized review of marketing application
- Enhanced opportunity for pre/post-market balance
- Efficient and flexible clinical study design
- Expedited review of preapproval manufacturing and quality systems compliance
- Preserves the statutory standards for marketing authorization

Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

Regulatory Context

- Program is statutorily mandated under Section 515B of the FD&C Act
- Guidance describes implementation
- Participation is voluntary for sponsors



Contains Nonbinding Recommendations

Breakthrough Devices Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 18, 2018.

The draft of this document was issued on October 25, 2017.

This document supersedes "Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions," issued on April 13, 2015.

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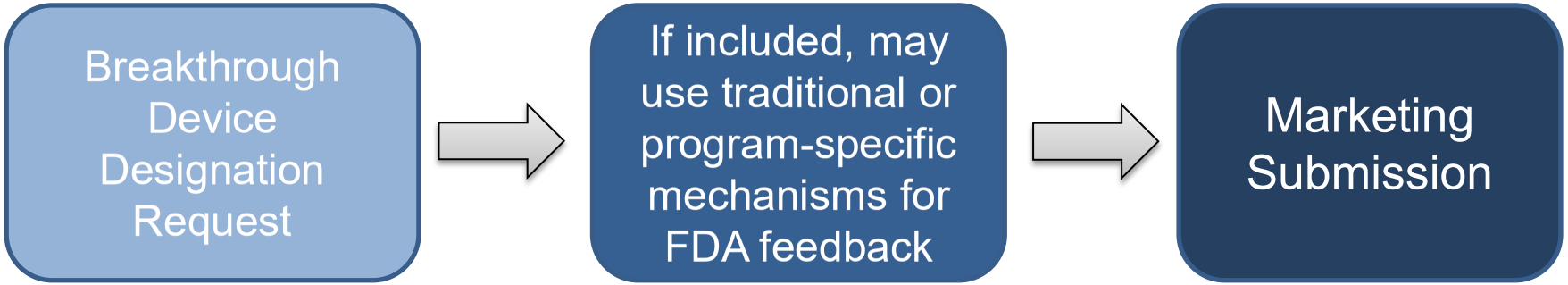
Program Overview



For devices granted Breakthrough Device designation:

- Designation tracks with the device for subsequent submissions
- Prioritized review and other benefits

Breakthrough Device Designation Criteria

Eligibility Considerations

- Medical devices and device-led combination products
- Subject to future marketing authorization via Premarket Approval (PMA), De Novo, or 510(k)
- Meets the Breakthrough criteria specified in Section 515B(b) of the FD&C Act
  - Must fully meet Breakthrough Device Criterion 1 AND one of the sub-parts of Breakthrough Device Criterion 2

Breakthrough Device Criterion #1

Criterion 1: provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions;

Reference: Section 515B(b)(1) of Food, Drug and Cosmetic Act

Considerations for “more effective”

- 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
  - Technical success: the device could function as intended
  - Clinical Success: a functioning device could more effectively treat or diagnose the identified disease or condition

- Mechanisms for demonstrating a reasonable expectation of technical and clinical success could include literature or preliminary data (bench, animal, or clinical)

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Considerations for disease/condition

- Life-threatening: a disease or condition for which the likelihood of death is high unless the course of the disease is interrupted in a population or subpopulation
  - Examples: acute stroke, myocardial infarction, cancer

- Irreversibly Debilitating: impact on such factors as survival, day-to-day functioning, and the likelihood that the disease or condition, if left untreated, will progress to a more serious disease or condition
  - Examples: amyotrophic lateral sclerosis (ALS)

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Breakthrough Device Criterion #2

Meets **one** of the following sub-parts in **Criterion 2**:

- 2A: that represent breakthrough technologies; or
- 2B: for which no approved or cleared alternatives exist; or
- 2C: that offer significant advantages over existing approved or cleared alternatives; or
- 2D: the availability of which is in the best interest of patients.

Reference: Section 515B (b)(2) of Food, Drug and Cosmetic Act

Breakthrough Devices Program Features

Breakthrough Devices Program Features

- Example features that sponsors can pursue:
  - Data Development Plan
    - Optional map of development process from entry into program until marketing submission & post-market activities as necessary
  - Sprint Discussion
    - Highly interactive process to facilitate reaching rapid agreement on a single development issue
  - Regular Status Updates
    - In between submissions, no feedback expectations
    - Useful for planning purposes

Marketing Submission

- For devices seeking Breakthrough Device designation, a request must be requested prior to marketing submission
- Program principles and benefits applied to marketing submission
  - Interactive and timely communication
  - Priority review
  - Senior management engagement
  - Pre/post-market balance when appropriate
- Statutory standard for marketing does not change

Summary

- The Breakthrough Devices Program is intended to provide patients and health care providers with timely access to breakthrough devices.
- Devices are designated by meeting the statutory criteria.
- Designated Breakthrough Devices can benefit from program features intended to expedite the development, assessment, and review of these devices.

Questions?