**Expedited Access Pathway (EAP)**
To Accelerate FDA Approval of Especially Innovative Medical Treatments or Devices

Dorothy B. Abel
Dorothy.Abel@FDA.HHS.GOV
Division of Cardiovascular Devices
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration

**Breakthrough Devices Program**
- **Expedited Access Pathway (EAP)**
  
  To Accelerate the Availability of Especially Innovative Medical Treatments or Devices

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**The Breakthrough Devices Program**
- December 13, 2016, the Breakthrough Devices provisions were added to the Food, Drug, and Cosmetic Act through section 3051 of the 21st Century Cures Act
- Will supersede the Expedited Access Pathway (EAP) and Priority Review Program
- Draft guidance on the Breakthrough Devices program was recently published and is out for comment (due by December 26, 2017)


**‘Expedited Access Programs’ are Mission Critical**
- **promote public health**
  - Intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review.
- **protect public health**
  - Preserves the statutory standards for getting to market through premarket approval, clearance of a premarket notification (510(k)), and marketing authorization via the De Novo classification process.

**Breakthrough Devices Program and Expedited Access Pathway**
- The Breakthrough Devices Program contains features of the:
  - EAP (launched in 2015)
  - Innovation Pathway (first piloted in 2011)
  - Voluntary
Eligibility

**EAP devices**
- address unmet medical needs for life-threatening or irreversibly debilitating diseases or conditions
- will be the subject of future Premarket Approval (PMA) applications and De Novo device submissions
- have a long-term “data-development plan” drafted

**Breakthrough Devices**
- provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
- will be the subject of future Premarket Approval (PMA) applications and De Novo device and 510(k) submissions
- have a long-term “data-development plan” drafted

Leaves room for including devices that have incremental benefits

Both approaches are intended for devices that address serious problems

With the new program also including 510(k) devices

Both programs cover PMA and De Novo device submissions
- have a long-term “data-development plan” drafted
Breakthrough Devices Program Designation

When:
• A request for designation may be made at any time prior to the submission of a PMA application or a 510(k) or De Novo submission—[preferably before finalizing the pivotal study plan]
• There can be multiple Breakthrough Device designations for the same intended use
• Can apply to combination devices


Designation Review Process

How:
• Submission of a stand-alone Q-Submission—Separate from the submission of a marketing or investigational device exemptions (IDE) application
• FDA will issue a grant or denial decision for each Breakthrough Device designation request within 60 calendar days of receiving such a request

Example Information to Include in a Designation Request

What:
• Background information
  – Device description
  – Indications for Use
  – Regulatory History
• Information to address the Designation Criteria
  – Criterion 1
    Device “provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions.”
  – Criterion 2
    Component options listed on next slide.
  – Planned marketing application

Statutory Designation Criterion 2

Multiple components of Criterion 2 may apply, but only one of the components must be met for Breakthrough Device designation

Device meets one of the criterion’s components below:
(A) that represent breakthrough technologies;
(B) for which no approved or cleared alternatives exist;
(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patient’s ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or
(D) the availability of which is in the best interest of patients.

The Philosophy and Approach
Principles

- Define approaches to expedite breakthrough device development, assessment and review
  - Guidance on optimize interactions and communications
  - Interactive and Timely Communication
  - Delineate the application of least burdensome principles
  - Pre/Postmarket Balance of Data Collection
  - Efficient and Flexible Clinical Study Design

Principles, cont.

- Commit to the appropriate allocation of resources and management oversight
  - Review Team Support
  - Senior Management Engagement
  - Priority Review
- Expedite the review of manufacturing and quality systems compliance
  - Manufacturing Considerations for PMA Submissions

Program Features

- To expedite the development of breakthrough devices, FDA intends to offer sponsors a menu of options that offer opportunities for early and regular interaction with FDA as device development unfolds.

Program Features

- Early-stage collaborations between the agency and sponsor on the device evaluation plan
  - Breakthrough Device Sprint Discussions
    - A more structured process for interacting on pre-clinical testing and clinical study designs
    - Each Sprint has a mutually agreed upon deadline
  - Collaboration on a development of a Data Development Plan (after acceptance in Program)
    - Outlining data collection expectations for the entire product lifecycle

Program Features

- Clinical Protocol Agreement
  - Written agreement
  - Binding, with qualifiers
  - Regular status updates

EAP Stats

- Since April 2015 when the EAP program launched
  - 83 requests for acceptance into the program received
    - 44 granted
    - 24 denied

EAP Stats

• Since April 2015 when the EAP program launched
  – 83 requests for acceptance into the program received
    • 44 granted
    • 24 denied
  – Some based on a lack of proof of concept
    » May be helpful to start with an Early Feasibility Study
  – Some associated with the need for a data-development plan
    » No longer needed to get into the program
  – Other reasons?

Good News

• For EAP, public feedback has been largely positive and participation has outpaced original estimates*

• Regarding the Breakthrough Devices Program
  – Is an evolution in expediting the development, assessment and review of breakthrough devices
  – Will include more structure for approaches to achieve the goals of the program