

Breakthrough Devices Program for Digital Health Products

The FDA [Breakthrough Devices Program](#) is a voluntary program to expedite the development and review of digital health products and device-led combination products that offer more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The program provides earlier patient access to these innovative medical devices while ensuring they meet appropriate standards for safety and effectiveness.



What is the program's purpose?

The program is designed to provide a streamlined and efficient regulatory pathway for digital health products that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions [e.g., Amyotrophic Lateral Sclerosis (ALS)].

What is the FDA's definition of life-threatening?

The FDA defines a life-threatening disease or condition as one for which the likelihood of death is high unless the course of the disease or condition is interrupted in a population or subpopulation.






Examples include acute stroke, myocardial infarction, cancer, etc.

What is the FDA's definition of irreversibly debilitating?

The FDA defines an irreversibly debilitating disease or condition as one that impacts factors such 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 include Multiple Sclerosis (MS), Amyotrophic Lateral Sclerosis (ALS), Muscular Dystrophy (MD), Cystic Fibrosis (CF), Poliomyelitis, etc.

Such definitions help patients receive more timely access to digital health products that treat or diagnose these diseases/conditions by expediting the development, assessment, and review of the products, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

 <p>Who is eligible for the program?</p>	<p>Digital health product developers with a product that provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions are eligible for the program.</p>	
 <p>What benefits does the program offer?</p>	<ul style="list-style-type: none"> ● Expedited FDA feedback/interaction ● Prioritized review of the product’s FDA marketing application ● Potential acceptance of greater uncertainty ● Enhanced opportunity for pre/post-market balance ● Efficient and flexible clinical study design ● Preservation of the statutory standards 	
 <p>When should the designation be requested?</p>	<p>One can submit a designation request for their product before submitting their FDA application, e.g, a premarket approval (PMA), premarket notification [510(k)], or De Novo classification request.</p>	
 <p>What are the program qualifications?</p>	<p>Products are eligible for breakthrough devices designation if they meet these criteria:</p> <ol style="list-style-type: none"> 1. The product provides for “more effective” treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions, and 2. At least one of the following statements applies to the product: <ol style="list-style-type: none"> a. It represents a breakthrough technology b. No approved or cleared alternatives exist c. It offers significant advantages over existing approved or cleared alternatives d. The availability of the product is in the best interest of patients 	
 <p>How is this program different from other FDA approval programs?</p>	<p>Breakthrough Designation</p> <p>Determines that a product is more effective than others the FDA has evaluated</p>	<p>Other FDA approval programs</p> <p>Determines that a product is at least as effective as (substantially equivalent) others the FDA has evaluated</p> <p>or</p> <p>Comprised of FDA evaluation of the data collected on a particular product in question</p>





How long does the designation process take?

60 days

(If additional information is required, the FDA will inform the submitter within 30 days of the original request submission)



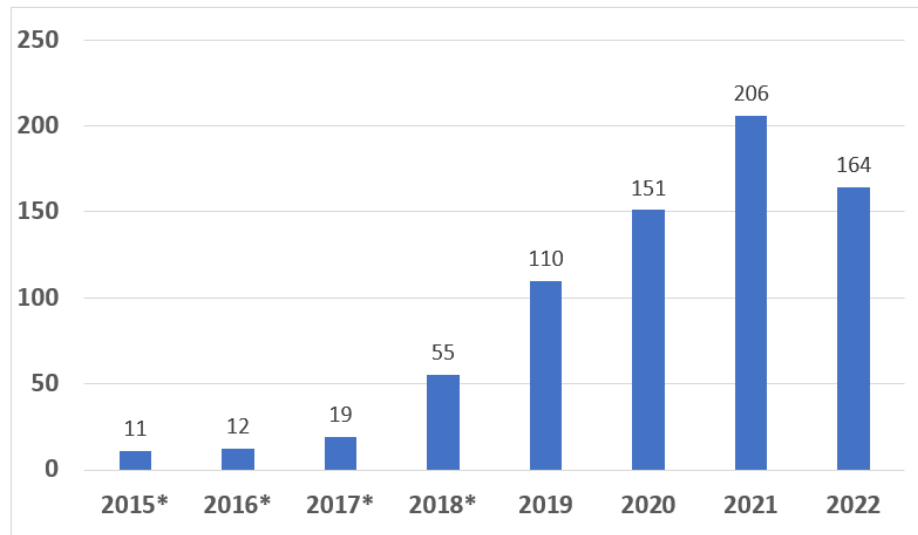
What is the participation fee for the program?

The fee associated with participating in the program is based on the type and complexity of the product, as well as the product's stage of development. The fee is intended to recover the costs associated with the FDA's review of the device.



How many products have been granted this designation?

As of 09/30/2022, **728 products** have been granted the Breakthrough Devices designation, a number that also includes products originally designated under the Expedited Access Pathway (EAP) program.

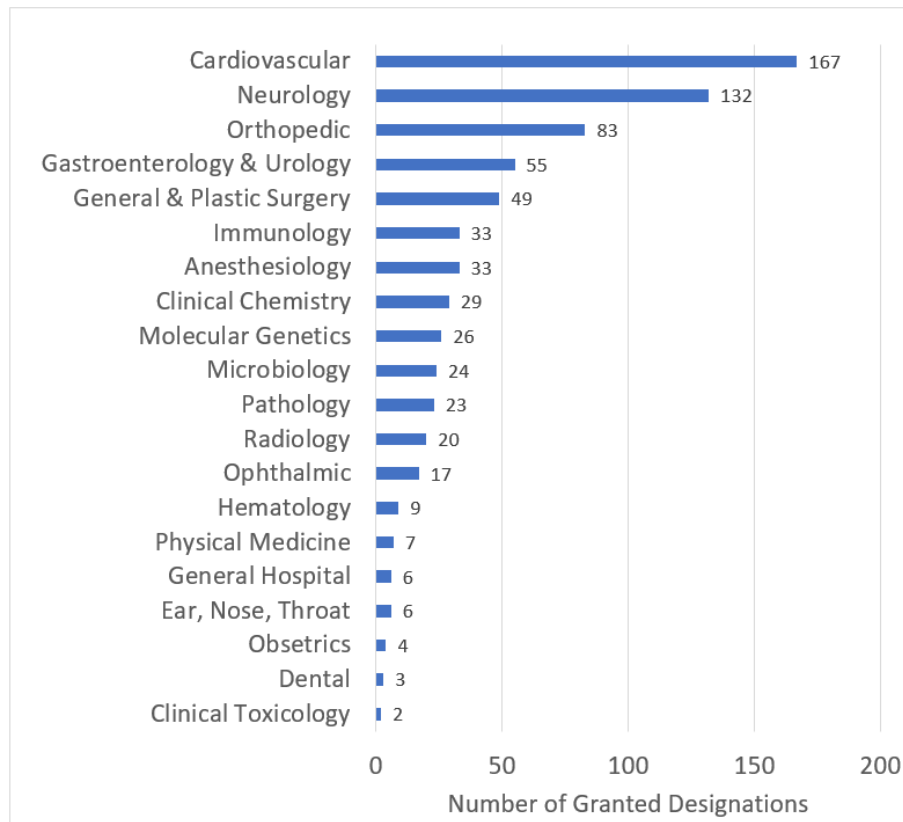


Source: [FDA](#)





What therapeutic areas have the designations been granted for?



Source: [FDA](#)



What if my product is not eligible?

For products that are not eligible for a Breakthrough Devices Designation because they are not intended for the treatment or diagnosis of a life-threatening or irreversibly debilitating human disease or condition, one may consider the [Safer Technologies Program](#).



Where can I find the list of products granted the designation?

- [FDA list](#)
- [STAT tracker](#)



Who should I contact for questions?

For any questions and inquiries related to the Breakthrough Devices program, email: BreakthroughDevicesProgram@fda.hhs.gov



Access DiMe's Digital Health Regulatory Pathway Resources



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