Can AI Devices Receive Breakthrough Device Designation?

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Abstract

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Introduction

Artificial intelligence (AI) is no longer a futuristic concept in healthcare; it's a present-day reality that is transforming patient care. From diagnostic imaging to personalized treatment plans, AI-powered medical devices are demonstrating immense potential to improve health outcomes. A key question for developers and healthcare professionals is whether these innovative AI devices can qualify for the U.S. Food and Drug Administration's (FDA) Breakthrough Device Designation. This designation is designed to expedite the development and review of medical devices that offer more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases. This article explores the eligibility of AI devices for this program, the benefits of the designation, and the future of AI in medical technology.

What is the Breakthrough Devices Program?

The FDA's Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions [1]. The program's goal is to provide patients and healthcare providers with timely access to these medical devices by speeding up their development, assessment, and review. The program offers manufacturers an opportunity to interact with FDA experts, receive feedback during the premarket review phase, and get prioritized review of their submissions [1].

To be eligible for Breakthrough Device Designation, a device must meet two main criteria:

1. It must be intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition. 2. It must meet at least one of the following: it represents a breakthrough technology; there are no approved or cleared alternatives; it offers significant advantages over existing approved or cleared alternatives; or its availability is in the best interest of patients [1].

Can AI Devices Qualify for Breakthrough Designation?

The answer is a resounding yes. AI-powered medical devices can and have received Breakthrough Device Designation. The key is to demonstrate that the device meets the program's stringent criteria. AI's ability to analyze vast amounts of data and identify patterns that may be missed by the human eye makes it a prime candidate for this designation, particularly in the realm of diagnostics.

A recent example is Aidoc, a company that received Breakthrough Device Designation for its AI-powered multi-triage solution [2]. This solution can flag a wide array of life-threatening, time-sensitive medical conditions from CT scans, helping care teams to prioritize high-risk cases. By significantly advancing the diagnosis of severe diseases, Aidoc's AI solution met the criteria for the designation. This case highlights how AI can provide a more effective diagnosis, which is one of the core tenets of the Breakthrough Devices Program.

The Process of Obtaining Breakthrough Designation

Manufacturers can request Breakthrough Device Designation at any time before submitting their marketing application. The request is submitted as a Q-Submission and should include a description of the device, its proposed indications for use, its regulatory history, and a detailed explanation of how it meets the Breakthrough Device criteria [1]. The FDA aims to make a decision on the designation within 60 days of receiving the request.

The Future of AI in Medical Devices and the Role of the Breakthrough Program

The FDA has been proactive in its approach to regulating AI-enabled medical devices. The agency has issued guidance documents and is actively working with stakeholders to ensure that these innovative technologies are safe and effective [3]. The Breakthrough Devices Program is a critical component of this effort, as it provides a clear pathway for developers of novel AI devices to bring their products to market more efficiently.

As of June 30, 2025, the FDA has granted 1,176 Breakthrough Device designations, and a significant number of these are for AI-powered devices [1]. This trend is expected to continue as AI technology becomes more sophisticated and its applications in healthcare expand. The program not only benefits manufacturers by accelerating the review process but also benefits patients by providing them with earlier access to potentially life-saving technologies.

Conclusion

AI devices are not only eligible for the FDA's Breakthrough Device Designation but are also increasingly receiving this recognition. By providing a more effective means of diagnosing and treating life-threatening and debilitating conditions, AI-powered medical devices are well-positioned to meet the program's criteria. The success of companies like Aidoc demonstrates the potential of AI to revolutionize healthcare, and the FDA's Breakthrough Devices Program is playing a crucial role in fostering this innovation. As AI continues to evolve, we can expect to see even more groundbreaking medical devices that will transform patient care for the better.

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