How a UK company navigated the FDA Breakthrough Devices Program

BY KEN BLOCK 21 OCTOBER 2020 08:00

Ken Block explains how Ken Block Consulting helped a UK-based company through the FDA Breakthrough Devices Program.

Recently, Ken Block Consulting helped our UK client Oxford Brain Diagnostics gain Breakthrough Device status from the FDA for its Cortical Disarray Measurement (CDM) Software Device, which is intended for evaluating adults at risk of Alzheimer's disease.

Other innovative companies in the UK and elsewhere could also benefit from this FDA status, but only with the right sort of technology and close attention to the proper regulatory approach. Here is an overview of the program and details of the application process that could be helpful to others.

Overview

Two years ago, the FDA introduced the Breakthrough Devices Program to formally recognise certain innovative and impactful new medical devices being developed for US market entry. Essentially replacing three former FDA programs (Innovation Pathway, Expedited Access Pathway and Priority Review Program), this new program is focused on medical devices (including IVDs) and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Upon entry to the program, eligible devices gain helpful FDA "fast track" advantages such as frequent meetings, senior FDA management involvement and priority review of the eventual device submission.

Manufacturers must pro-actively author an appropriate Q-Submission to the FDA to apply for this new program. The Q-Sub must not only thoroughly explain the new device and proposed intended use, but also convince the FDA review team that the

device meets specific criteria spelled out in the aptly named FDA guidance document Breakthrough Devices Program.

Acceptance into the program grants Breakthrough Device status to the proposed medical device, which then triggers a close collaborative working relationship between the medtech company and the FDA. This focussed collaboration includes mutual agreement on the objective evidence that will be necessary for an eventual premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request ("De Novo request") for the proposed device.

Criteria

As an example of how novel and important technology can qualify for Breakthrough Devices Program, we will next examine the Oxford Brain Diagnostics technology in comparison to the FDA criteria.

We started working closely with Oxford Brain Diagnostics immediately after helping another of our startup clients gain Breakthrough Device status from the FDA. Because the CDM Software Device meets the International Medical Device Regulators Forum (IMDRF) definition of Software as a Medical Device (SaMD), the Q-Sub to FDA was logically written somewhat differently from our prior successful Breakthrough Device for hardware-intensive technology. However, it is important to understand that the Breakthrough Device criteria are the same for SaMD as for other device types. Therefore, the principles of a successful Breakthrough Device application to FDA are consistent regardless of technology or intended use. As with any FDA submission, success requires not only understanding the detailed FDA regulatory requirements, but also having the practical methodology to meet those requirements and highly interactive exchange of information between consultancy and client staff.

To be accepted into the Breakthrough Devices Program, the authored Q-Sub must convince the FDA review team that the proposed device meets designation criterion 1 and one or more items under designation criterion 2, as discussed below. The CDM Software Device satisfied criterion 1 and all aspects under criterion 2.

Program criterion 1

FDA Breakthrough Devices must "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" – so this special FDA program is reserved for those technologies that address important patient healthcare situations. Because the CDM Software Device is addressing diagnosis of an irreversibly debilitating disease (i.e., Alzheimer's), our client's technology fit seamlessly into this first criterion.

Program criterion 2A

FDA Breakthrough Devices must "represent breakthrough technologies" – and there are two keys to satisfying this criterion. The first is convincing the FDA review team that the proposed device (once fully developed) will provide users/patients with a device that is better than the currently available Standard of Care (SOC). The second key is to author forceful arguments that the proposed device has a reasonable expectation to function as intended (technical success) and that the functioning device will more effectively treat or diagnose the identified disease or condition (clinical success), based on the

company's progress to date. Given this requirement, companies cannot gain Breakthrough Device status simply for some medtech concept or patentable idea. Having been spun out from research conducted at Oxford University, the CDM Software Device had already generated results for predicting Alzheimer's disease in patients diagnosed with Mild Cognitive Impairment (MCI) by using novel software algorithms to evaluate MRI brain scan data, successfully addressing criterion 2A.

Program criterion 2B

FDA Breakthrough Devices must have "no approved or cleared alternatives" on the US market. Although seemingly counterintuitive, Breakthrough Devices can have a 510(k) pathway (which requires that a "substantially equivalent" predicate device already exist on the US market). However, the key to this criterion is the intended use of the proposed Breakthrough Device – which should differ in some manner from the possible US market alternates. In the case of the CDM Software Device, accurate early prediction of Alzheimer's disease diagnosis using SaMD represents something completely new for the US market.

Program criterion 2C

FDA Breakthrough Devices must "offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalisation, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies" – a criterion that offers several pathways to satisfaction. In the case of Alzheimer's disease, the current SOC makes the diagnosis after the patient is already suffering from an irreversible, debilitating condition. The CDM Software Device will allow patients the ability to plan and manage their care while only suffering from the less debilitating condition of MCI. As a predictive SaMD, clinical efficiencies should increase significantly with a more certain Alzheimer's disease prognosis.

Program Criterion 2D

FDA Breakthrough Devices must provide "availability of which is in the best interest of patients." By identifying in advance whether patient conditions will worsen to Alzheimer's disease, the CDM Software Device enables advanced planning for care and encourages risk-reducing lifestyle changes, helping patients stay at home with their family for longer. The SaMD could also enable patient enrollment into pharmaceutical clinical trials for access to potential new drugs, thereby supporting the broader public health objective of developing new treatments addressed by this criterion.

Summary

Highly impactful and novel medical device technologies can gain "fast track" advantages from the FDA, when companies thoroughly understand and successfully address the necessary criteria for the Breakthrough Devices Program.

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