
Apple Watch Receives FDA Approval as MDDT



The Food and Drug Administration (FDA) has made history by granting the Apple Watch approval as a digital health technology device. Specifically, the FDA has endorsed its atrial fibrillation (AFib) feature as a qualified tool in the Medical Device Development Tools (MDDT) programme. This feature aids in detecting irregular heart patterns and has been previously recognised for its life-saving capabilities.

This FDA approval permits the use of the Apple Watch's AFib feature to evaluate atrial fibrillation burden estimates within clinical studies. This is a significant milestone for Apple, as the AFib feature can now serve as a noninvasive biomarker test to assess AFib burden, a secondary effectiveness endpoint in clinical studies aimed at assessing the safety and effectiveness of cardiac ablation devices for treatment.

With this achievement, the Apple Watch AFib feature has become a pioneering digital health technology that qualifies under the FDA's MDDT programme. While the Apple Watch had previously obtained FDA clearance to integrate its atrial fibrillation detection feature in 2022, this latest endorsement elevates its status, particularly in the realm of clinical research.

The electrocardiogram feature on the Apple Watch can determine if the user has an irregular heartbeat. With the AFib History feature, users can track their heart events, enabling those with the condition to see an estimate of how often their hearts experience irregular rhythms.

The AFib History feature utilises pulse rate data gathered by the Apple Watch photoplethysmography (PPG) sensor. It identifies instances of irregular heart rhythms aligned with AFib and furnishes the user with a retrospective estimate of AFib burden. This measurement gauges the duration of AFib occurrences during previous periods of Apple Watch usage.

The FDA announced that the Apple Watch is now approved for use in clinical studies. According to the report, this approval signifies that it is "intended for use... prior to and following cardiac ablation procedures, for monitoring a study participant's weekly estimate of AFib burden."

The FDA process is rigorous, meticulously assessing supporting evidence to ascertain accuracy and suitability for scientifically valid measurements within specific contexts. Consequently, gaining FDA approval is a notable accomplishment for Apple.

Source: [Forbes](#)

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