

FDA qualifies Apple Watch's AFib history for use in clinical studies

The Apple Watch's atrial fibrillation (AFib) history feature, which records and alerts the wearer's relevant heart events, has been qualified to join the FDA's Medical Device Development Tools (MDDT) program – a first for a “digital health technology.” That means the Apple Watch is now usable in clinical studies that need estimated data on how much time the wearer spent in atrial fibrillation while wearing the device, *9to5Mac* reports.

The FDA announcement describes using it as a noninvasive way to collect the data both before and after treatment:

Designed to be used as a biomarker test to help evaluate estimates of AFib burden as a secondary effectiveness endpoint within clinical studies intended to evaluate the safety and effectiveness of cardiac ablation devices to treat.

Apple has long touted its watch as a lifesaver for those who wear one. Features such as fall detection and car crash detection have been credited with saving lives. Apple often cites Apple Watch customer anecdotes in its marketing who say they visited their doctors after receiving heart-related alerts on their wrists – which potentially saved their lives. However, added anxiety from extra data could also be detrimental.

The FDA previously granted clearance to two Apple Watch

functions as a direct-to-consumer wearable device with an electrocardiogram and to notify you if you have an irregular heartbeat, starting with the Series 4 in 2018. It also specified that the apps are “not intended to replace traditional methods of diagnosis or treatment” – if you feel off or have questions, you should still rely on a real doctor. The Apple Watch doesn’t diagnose conditions, and one study suggested treatments for the conditions don’t fit the typical Apple Watch user.

<https://www.theverge.com/2024/5/2/24147178/fda-apple-watch-mdd-t-qualification-afib-history>