FDA 510(k) Premarket Notification

CLEARED

K250507 Hypertension Notification Feature (HTNF)

Sep 11, 2025
202 days to decision

K250507 · Product code: **SFR** · Cardiovascular
Source: https://www.510kdatabase.net/k250507/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hypertension Machine Learning-based Notification Software (SFR)
Date received	Feb 21, 2025
Decision date	Sep 11, 2025
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Apple, Inc.**
Location	Alexandria, VA, US
Contact	Bonnie Wu
Website	http://www.apple.com/it/
510(k) history	12 submissions · 9 cleared · 2018-2026

Apple, Inc. is a technology company that develops consumer electronics and digital health solutions. The company operates with a manufacturing facility in Alexandria, US, and has expanded into medical device development through FDA-regulated health features integrated into its consumer products. Apple has received FDA 510(k) clearances from total submissions since its first clearance in 2018. The company's cleared devices focus primarily on cardiovascular monitoring and ophthalmic applications, with recent clearances including notification features for hypertension, irreg...