FDA 510(k) Premarket Notification

CLEARED

K213971 Atrial Fibrillation History Feature

Jun 3, 2022
165 days to decision

K213971 · Product code: **QDB** · Cardiovascular
Source: https://www.510kdatabase.net/k213971/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Photoplethysmograph Analysis Software For Over-the-counter Use (QDB)
Date received	Dec 20, 2021
Decision date	Jun 3, 2022
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Apple, Inc.**
Location	Alexandria, VA, US
Contact	Luke Olson
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...