FDA 510(k) Premarket Notification

K201525 ECG App

CLEARED

Oct 8, 2020
122 days to decision

K201525 · Product code: **QDA** · Cardiovascular
Source: https://www.510kdatabase.net/k201525/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph Software For Over-the-counter Use (QDA)
Date received	Jun 8, 2020
Decision date	Oct 8, 2020
Days to decision	122 days
Third-party review	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...