

K200948 Fitbit ECG AppSep 11, 2020
156 days to decisionK200948 · Product code: **QDA** · Cardiovascular
Source: <https://www.510kdatabase.net/k200948/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph Software For Over-the-counter Use (QDA)
Date received	Apr 8, 2020
Decision date	Sep 11, 2020
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fitbit, Inc.
Location	Fairfax, VA, US
Contact	Shruti Rajagopalan
510(k) history	3 submissions · 3 cleared · 2014-2022

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