CLEARED

K212372 Fitbit Irregular Rhythm Notifications

Apr 8, 2022
252 days to decision

K212372 · Product code: **QDB** · Cardiovascular
Source: https://www.510kdatabase.net/k212372/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Photoplethysmograph Analysis Software For Over-the-counter Use (QDB)
Date received	Jul 30, 2021
Decision date	Apr 8, 2022
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

CLINICAL EVIDENCE - NCT04380415

Validation of Software for Assessment of Atrial Fibrillation From PPG Data Acquired by a Wearable Smartwatch

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	450000 patients (actual)
Study sites	2 sites
Condition studied	Atrial Fibrillation
Primary purpose	Diagnostic
Study type	Interventional
Study design	Sequential
Masking	Single blind
Completion date	Mar 8, 2021
Sponsor	Fitbit LLC (Industry)

Primary outcome

Simultaneous measurement of AF ? 30 seconds with detection

Secondary outcome

Simultaneous measurement of AF ? 30 seconds with pulse tachograms

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04380415