FDA 510(k) Premarket Notification

CLEARED

K213357 Study Watch with Irregular Pulse Monitor (Home), Study Watch with Irregular Pulse Monitor

Jul 19, 2022
280 days to decision

K213357 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k213357/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Oct 12, 2021
Decision date	Jul 19, 2022
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Verily Life Sciences, LLC**
Location	South San Francisco, CA, US
Contact	Dinesh Puppala
510(k) history	4 submissions · 4 cleared · 2019-2024

CLINICAL EVIDENCE - NCT04546763

Study Watch AF Detection At Home

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	117 patients (actual)
Study sites	5 sites
Condition studied	Atrial Fibrillation
Study type	Observational
Completion date	May 14, 2021
Sponsor	Verily Life Sciences LLC (Industry)

Primary outcome

Accuracy of AF detection - Sensitivity

Secondary outcome

A sensitivity analysis estimating the range of sensitivities

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04546763