FDA 510(k) Premarket Notification

CLEARED

K243236 WHOOP ECG (electrocardiogram) Feature (1.0)

Apr 4, 2025
176 days to decision

K243236 · Product code: **QDA** · Cardiovascular
Source: https://www.510kdatabase.net/k243236/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph Software For Over-the-counter Use (QDA)
Date received	Oct 10, 2024
Decision date	Apr 4, 2025
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Whoop., Inc.**
Location	Boston, MA, US
Contact	Nikki Batista
510(k) history	1 submissions · 1 cleared · 2025-2025

CLINICAL EVIDENCE - NCT06622265

WHOOP ECG Software Performance Assessment Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	540 patients (actual)
Study sites	7 sites
Condition studied	Atrial Fibrillation (AF)
Study type	Observational
Completion date	Jul 3, 2024
Sponsor	Whoop Inc. (Industry)

Primary outcome

Specificity of the WHOOP ECG Feature for detection of sinus rhythm

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06622265