FDA 510(k) Premarket Notification

K241633 Informed Vital Core Application (IVC App)

CLEARED

Nov 18, 2024
165 days to decision

K241633 · Product code: **QME** · Cardiovascular
Source: https://www.510kdatabase.net/k241633/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software For Optical Camera-based Measurement Of Pulse Rate, Heart Rate, Breathing Rate, And/or Respiratory Rate (QME)
Date received	Jun 6, 2024
Decision date	Nov 18, 2024
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mindset Medical, Inc.**
Location	Phoenix, AZ, US
Contact	Chris Joslin
510(k) history	2 submissions · 2 cleared · 2024-2025

CLINICAL EVIDENCE - NCT05853380

A Multi-Center Prospective Open Label Study of a Web-based Application for Pulse Rate in Adult Patients

Status	Completed
Enrollment	86 patients (actual)
Study sites	6 sites
Condition studied	Vital Sign Evaluation
Study type	Observational
Completion date	Jun 29, 2023
Sponsor	Mindset Medical (Industry)

Primary outcome

Pulse Rate Accuracy

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05853380