FDA 510(k) Premarket Notification

CLEARED

K250078 Informed Vital Core Application (IVC App) (v2.0.0.2.0.0)

May 30, 2025
137 days to decision

K250078 · Product code: **QME** · Cardiovascular
Source: https://www.510kdatabase.net/k250078/

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	Jan 13, 2025
Decision date	May 30, 2025
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

CLINICAL EVIDENCE - NCT06508047

Respiratory Rate Validation Study - Mindset Medical Informed Vital Core Application

Status	Completed
Enrollment	68 patients (actual)
Study sites	1 site
Condition studied	Vital Sign Evaluation
Study type	Observational
Completion date	Aug 22, 2024
Sponsor	Mindset Medical (Industry)

Primary outcome

Respiratory Rate Accuracy

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06508047