FDA 510(k) Premarket Notification

K233953 Makani Science™ Respiration Monitoring System

CLEARED

Mar 28, 2025
469 days to decision

K233953 · Product code: **BZQ** · Anesthesiology
Source: https://www.510kdatabase.net/k233953/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Dec 15, 2023
Decision date	Mar 28, 2025
Days to decision	469 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Makani Science, Inc.**
Location	Irvine, CA, US
Contact	Michael Chu
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Speed TO Market, Inc.**
Contact	Thomas Kroenke

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT06000852

Comparison of Non-Invasive Respiratory Monitoring System (RMS)

Status	Completed
Enrollment	27 patients (actual)
Condition studied	Respiratory Monitoring
Primary purpose	Basic_science
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Oct 29, 2022
Sponsor	Michael Chu (Industry)

Primary outcome

Respiratory Rate Accuracy Between the Respiratory Monitoring System and Manual Counting by a Trained Professional for the Supine Position

Secondary outcome

Respiratory Rate Bias Between the Respiratory Monitoring System and Manual Counting by a Trained Professional for the Supine Position

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06000852