

K243183 RTMsense Respiratory Monitoring SystemJun 27, 2025
270 days to decisionK243183 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k243183/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Sep 30, 2024
Decision date	Jun 27, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rtm Vital Signs, LLC
Location	Ambler, PA, US
Contact	Dicciani Nance
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Mededge Consulting
Contact	Billi-Jo Pfalzgraf

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

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