



July 30, 2025

RTM Vital Signs, LLC  
% Billi-Jo Pfalzgraf  
Regulatory Consultant  
MedEdge Consulting  
7005 Evergreen Place  
Roswell, Georgia 30076

Re: K243183

Trade/Device Name: RTMsense Respiratory Monitoring System  
Regulation Number: 21 CFR 868.2375  
Regulation Name: Breathing Frequency Monitor  
Regulatory Class: Class II  
Product Code: BZQ

Dear Billi-Jo Pfalzgraf:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative error related to your previous substantial equivalence (SE) determination letter dated June 27, 2025. Specifically, FDA is updating this SE Letter as an administrative correction to revise the trade name from RTM Sense (A-0001) to RTMsense Respiratory Monitoring System and to revise the regulation name from Monitoring Spirometer to Breathing Frequency Monitor.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Rachana Visaria, Ph.D., OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, [Rachana.Visaria@fda.hhs.gov](mailto:Rachana.Visaria@fda.hhs.gov).

Sincerely,

**Rachana Visaria -S**

Rachana Visaria, Ph.D.  
Assistant Director  
DHT1C: Division of Sleep Disordered  
Breathing, Respiratory and  
Anesthesia Devices  
OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



June 27, 2025

RTM Vital Signs, LLC  
% Billi-Jo Pfalzgraf  
Regulatory Consultant  
MedEdge Consulting  
7005 Evergreen Place  
Roswell, Georgia 30076

Re: K243183

Trade/Device Name: RTM Sense (A-0001)

Regulation Number: 21 CFR 868.2375

Regulation Name: Monitoring spirometer

Regulatory Class: Class II

Product Code: BZQ

Dated: May 21, 2025

Received: May 21, 2025

Dear Billi-Jo Pfalzgraf:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Binoy J.  
Mathews -S** Digitally signed by  
Binoy J. Mathews -S  
Date: 2025.06.27  
12:00:23 -04'00'

For

Rachana Visaria PhD.  
Assistant Director  
DHT1C: Division of Anesthesia,  
Respiratory, and Sleep Devices  
OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT, and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K243183

Device Name  
RTMsense Respiratory Monitoring System

### Indications for Use (Describe)

The RTMsense Respiratory Monitoring System is indicated for use by healthcare professionals in healthcare facilities, such as post-operative care and general wards, to monitor breathing in adult (at least 22 years old) patients.

RTMsense Respiratory Monitoring System is a non-invasive system that graphically displays respiratory function against time and reports respiratory rate. RTMsense Respiratory Monitoring System measurements are used as an adjunct to other clinical information sources.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# RTMsense Respiratory Monitoring System 510(k)

## 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

**Date:** June 27, 2025

### 1.0 SUBMITTER:

RTM Vital Signs, LLC  
8 Richards Way  
Ambler, PA 19002-2532

### 1.1 PRIMARY CONTACT PERSON:

Billi-Jo Pfalzgraf  
Regulatory Consultant  
MedEdge Consulting  
(707) 799-6732  
[bjpfalzgraf@mededge.io](mailto:bjpfalzgraf@mededge.io)

### 1.2 SECONDARY CONTACT PERSON:

Tiffini Wittwer  
Regulatory Consultant and Owner  
MedEdge Consulting  
(707) 799-6732  
[twittwer@mededge.io](mailto:twittwer@mededge.io)

### 2.0 DEVICE:

Trade Name:	RTMsense Respiratory Monitoring System
Regulation Name:	Breathing Frequency Monitor
Regulation Number:	21 CFR 868.2375
Regulatory Class:	II
Product Code:	BZQ

### 3.0 PREDICATE DEVICE:

The subject device is substantially equivalent to the following devices:

510(k) Number	Predicate Device Name / Manufacturer	Primary Predicate	Reference Predicate
K242798	Airmod™ / Heroic Faith International, Ltd.	✓	
K242971	AccurSound Electronic Stethoscope AS101		✓
K120984	Masimo Acoustic Monitoring Sensors		✓

### 4.0 DEVICE DESCRIPTION:

The RTMsense Respiratory Monitoring System is a single use wearable device consisting of a wearable trachea sound sensor (TSS) and software that continuously measures a patient's respiratory rate by analyzing the sounds of air flow within the proximal trachea during inhalation and exhalation. The acoustic signal is transmitted wirelessly to a Lenovo Tablet, and the respiratory measurement values are displayed on the tablet after analysis of the acoustic data by a proprietary software algorithm.

The RTMsense software application has three parts: firmware on the TSS, a web-based application on the Lenovo tablet, and a cloud-based proprietary software algorithm. The TSS securely transmits acoustic data wirelessly to the local, Bluetooth low energy enabled Lenovo tablet. The tablet uses a web-based application to securely transmit the acoustic data to the cloud for analysis in RTM's proprietary cloud-based algorithm. The web application retrieves the processed data from the algorithm to display respiratory rate on the tablet.

The device will be used by healthcare professionals in healthcare facilities such as post-operative care or general wards. The RTMsense respiratory measurements are used as an adjunct to other clinical information sources.

The TSS is held in place by a flexible wearable carrier adhered to the patient's proximal trachea with commercially available medical grade adhesive. The TSS contains the audio sensor, onboard processing, wireless communications technology, and Lithium-ion coin cell rechargeable battery. A custom charger is provided to charge the battery.

#### **5.0 INDICATIONS FOR USE:**

The RTMsense Respiratory Monitoring System is indicated for use by healthcare professionals in healthcare facilities, such as post-operative care and general wards, to monitor breathing in adult (at least 22 years old) patients.

RTMsense Respiratory Monitoring System is a non-invasive system that graphically displays respiratory function against time and reports respiratory rate. RTMsense Respiratory Monitoring System measurements are used as an adjunct to other clinical information sources.

#### **6.0 SUBSTANTIAL EQUIVALENCE:**

The subject RTMsense Respiratory Monitoring System is similar to the predicate in several ways. Both devices provide continuous, non-invasive monitoring of respiratory rate in adult patients. Both devices graphically display respiratory rate against time and use acoustic signals produced by turbulent airflow in the trachea during inhalation and exhalation as respiratory measure method. Both devices use their own proprietary software algorithm to calculate respiratory parameters. The subject and predicate devices have the same sensor application site and similar intended use, indication for use, and use environment. Performance and safety testing has demonstrated that technical differences do not raise new questions of safety and effectiveness. Thus, the subject RTMsense Respiratory Monitoring System is substantially equivalent to the predicate, Heroic Faith International Airmod™ device.

The table below compares the intended use and technological characteristics of the subject and predicate device.

Feature	RTM Vital Signs RTMsense (Subject Device)	Heroic Faith International Airmod™ System (Predicate Device)	Heroic Faith International AccurSound Electronic Stethoscope AS-101 (Reference Device)	Masimo Corporation Acoustic Monitoring Sensors (Reference Device)	Similarities and Differences
510(k)	K243183	K242798	K242971	K120984	
Class	II	II	II	II	Same as predicate and reference
Regulation	21 CFR 868.2375	21 CFR 868.2375	21 CFR 870.1875	21 CFR 870.2700	Same as predicate
Common Name	Breathing Frequency Monitor	Breathing Frequency Monitor	Electronic Stethoscope	Pulse Oximeter	Same as predicate
Product Code	BZQ	BZQ	DQD	DQA, BZQ	Same as predicate and Masimo reference
Indications for Use	<p>The RTMsense Respiratory Monitoring System is indicated for use by healthcare professionals in healthcare facilities, such as post-operative care and general wards, to monitor breathing in adult (at least 22 years old) patients.</p> <p>RTMsense Respiratory Monitoring System is a non-invasive system that graphically displays respiratory function against time and reports respiratory rate. RTMsense Respiratory Monitoring System measurements are used as an adjunct to other clinical information sources.</p>	<p>Airmod, when used in conjunction with AccurSound Electronic Stethoscope AS-101, is a software as medical device intended to be used for the continuous, non-invasive monitoring or respiratory rate (RR) in adult patients who are subjected to procedural sedation and/or anesthesia. Airmod is intended for use by healthcare professionals in hospitals and healthcare facilities who are legally credentialed to perform procedural sedation and/or anesthesia. Airmod is intended for Android-based devices only.</p>	<p>The AS-101 is an electronic stethoscope intended for the detection and amplification of sounds associated with the heart, lungs, arteries, veins, and other internal organs. It can be used on any person undergoing a physical assessment. The device is intended to be operated only by healthcare professionals for diagnostic decision support in clinical settings.</p>	<p>The Rainbow Acoustic Monitoring sensors and cables are indicated for continuous, noninvasive monitoring of respiratory rate (RRa). The RAS-125 is indicated for adult patients in hospitals, hospital-type facilities, mobile, and home environments. The RAS-125c is indicated for adult and pediatric patients in hospitals, hospital-type facilities, mobile, and home environments.</p>	<p>Similar to predicate and Masimo reference.</p>
Patient Population	Adults	Adults undergoing procedural sedation and/or anesthesia	Adults, pediatrics, or infants undergoing a physical assessment	Adults and pediatrics (>2 yr)	Similar to Masimo reference (for adults)
Use Environment	Non-critical post-operative care and general wards	Hospitals and healthcare facilities	Clinical settings	Hospitals, hospital-type facilities, mobile, and home environments	Similar. Narrower use environment does not raise new questions of safety or effectiveness.
Device Components	Hardware (sensor and tablet) Software	Software	Hardware (sensor, cable, earphone, power adapter) Software	Hardware (sensor, connection cable, monitor) Software	Similar to Primary Predicate and Masimo reference

Feature	RTM Vital Signs RTMsense (Subject Device)	Heroic Faith International Airmod™ System (Predicate Device)	Heroic Faith International AccurSound Electronic Stethoscope AS-101 (Reference Device)	Masimo Corporation Acoustic Monitoring Sensors (Reference Device)	Similarities and Differences
Sensor Technology	Acoustic	Acoustic	Acoustic	Acoustic	Same
Continuous or Intermittent Monitoring	Continuous, Real Time	Continuous, Real Time	Intermittent	Continuous, Real Time	Same as predicate and Masimo reference
Apnea Monitoring	No	No	No	No	Same
Wireless Device	Yes	N/A	No	No	Different. Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2, wireless coexistence testing, and device performance validation testing demonstrate this difference does not raise new questions of safety and effectiveness.
Respiratory Measure Method	Acoustic signals produced by the turbulent airflow in the trachea during inhalation and exhalation	Acoustic signals produced by the turbulent airflow in the upper airway during inhalation and exhalation	N/A	Acoustic signals produced by the turbulent airflow in the upper airway during inhalation and exhalation	Similar. Performance testing and Software Algorithm validation demonstrate this difference does not raise new questions of safety and effectiveness.
Rate Measure	Respiratory Rate (breaths/min)	Respiratory Rate (breaths/min)	N/A	Respiratory Rate (breaths/min)	Same as predicate and Masimo reference
RR Range and Accuracy	8-22 ± 1 BPM	4-35 ± 2.7 BPM	N/A	4 – 70 ± BPM	Similar. Narrower range of respiratory rate does not raise new questions of safety or effectiveness.
Algorithm	Proprietary software algorithm calculates respiratory parameters using advanced signal-processing methods to extract specific information from tracheal sounds.	Signal processing algorithms convert the acoustic patterns into breath cycles to calculate respiration rate.	Auscultation sound is digitally processed, filtered, and electronically amplified	Masimo SET® acoustic signal processing to extract RRA and waveform	Performance testing and Software Algorithm validation demonstrate this difference does not raise new questions of safety and effectiveness.
Alerts/Alarms	No	Yes	No	Unknown	Subject device is intended for adjunctive use and not indicated for use in critical care settings. Similar to K240251.
Sensor Application Site	Neck	Neck	Multiple locations	Neck	Same as predicate and Masimo reference

<b>Feature</b>	<b>RTM Vital Signs RTMsense (Subject Device)</b>	<b>Heroic Faith International Airmod™ System (Predicate Device)</b>	<b>Heroic Faith International AccurSound Electronic Stethoscope AS-101 (Reference Device)</b>	<b>Masimo Corporation Acoustic Monitoring Sensors (Reference Device)</b>	<b>Similarities and Differences</b>
Reusable	No	N/A, device is software	Yes	No	Same as Masimo reference
Power Source	Lithium Ion Battery	N/A	AC/DC	External source	Different. Electrical safety testing in accordance with IEC 60601-1 demonstrates this difference does not raise new questions of safety and effectiveness.

**7.0 PERFORMANCE DATA:**

The following performance data were provided in support of the substantial equivalence determination:

Applicable Standards and Guidances

- Biocompatibility
  - ISO 10993-1 Fifth edition, 2018-08 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
  - FDA Guidance, “Use of International Standard ISO 10993-1, “Biological Evaluations of Medical Devices Part 1: Evaluation and testing within a risk management process” ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
  - ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
  - ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Electrical Safety and Electromagnetic Compatibility
  - IEC 60601-1 Edition 3.2 2020-08 Consolidated Version – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
  - IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
  - IEEE ANSI USEMCSC C63.27-2021 – American National Standard for Evaluation of Wireless Coexistence
- User Validation
  - IEC 62366-1 Edition 1.1 2020-06 Consolidated Version – Medical Devices – Part 1: Application of usability engineering to medical devices
- Risk Management
  - ISO 14971 Third edition 2019-12 - Medical Devices – Application of risk management to medical devices
- Software/Cybersecurity
  - Content of Premarket Submissions for Device Software Functions: 2023
  - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: 2025

Non-Clinical Performance Testing

Test	Test Method Summary	Results
Connection and Data Transmission	Devices were tested to demonstrate that it can successfully connect and transmit data in real-time to web-based application.	Passed. All devices met performance criteria. This testing is relevant in determining substantial equivalence because the subject device and predicate both provide continuous patient monitoring. The reliability of the subject device’s wireless connection supports substantial equivalence to the predicate.

Signal Output	Devices were tested to demonstrate the output signal of the device and software is adequate to calculate respiratory rate.	Passed. All systems met performance criteria. This testing is relevant in determining substantial equivalence because it demonstrates the subject device's respiratory measurement method can be used to monitor breathing in adult patients and do not raise new questions of safety and effectiveness.
Graphical User Interface (GUI)	Devices were tested to demonstrate connection via BLE and data transmission to Web App through Chrome browser on a Lenovo tablet.	Passed. This is relevant to determining substantial equivalence because the subject device and predicate both provide a graphical user interface to display and report respiratory measurements.
Battery Voltage	Testing was conducted to ensure battery provided sufficient voltage and can be recharged.	Passed. This testing is relevant to determining substantial equivalence because the subject device is battery powered while the predicate devices is AC powered.
Adhesion Testing	Adhesion testing was conducted to demonstrate the device would remain secured to patient's proximal trachea during normal use for the entire monitoring period.	Passed. This testing is relevant to determining substantial equivalence because it demonstrates the wearability of the subject device.
Performance Validation: Simulated Use	Devices were placed on multiple subjects to demonstrate the device captures, records, and transmits acoustic breathing sounds that are analyzed against time and displayed on a graphical user interface.	Passed. This testing is relevant to determining substantial equivalence because it demonstrates the device performs as intended and meets the user needs.
Software Verification / Validation Testing	Integration and algorithm testing was conducted to verify the software meets its requirements and accurately reports respiration rate.	Passed. This testing is relevant to determining substantial equivalence because it demonstrates the software functions as intended.

Clinical Performance Testing:

Clinical validation was performed to evaluate the performance of the RTMsense Respiratory Monitoring System. Two prospective comparative studies were conducted to assess the accuracy against gold standard respiratory measurements. Combined, the studies included 44 subject and over 150 breath samples. The first study was a prospective, comparative study totaling 31 subjects and 124 breath samples. The second study was a prospective study totaling 13 subjects and 65 breath samples. Respiratory rates were simultaneously collected using the RTMsense Respiratory Monitoring System and the Hamilton C-1 Ventilator with integrated Capnostat 5 capnometer. Manually scored End-Tidal CO<sub>2</sub> breath counts from the capnometer were used as the gold standard reference to compare to RTMsense. Primary endpoints assessed were accuracy  $\leq$  1 BPM and mean accuracy error  $<$  5%.

### Summary Table of Results Study #1

Manual ETCO <sub>2</sub> RR (b/min) Mean±SD	RTMsense RR (b/min) Mean±SD	Mean Absolute Bias ±SD (b/min)	% Error	Bias	Mean Absolute Error
14.18±3.32	14.04±3.43*	0.14±0.72	2.30	0.29	0.58

\*Intraclass correlation coefficient was 0.989 and 0.994 (p<0.0001)

### Summary Table of Results Study #2

Manual ETCO <sub>2</sub> RR (b/min) Mean±SD	RTMsense RR (b/min) Mean±SD	Mean Absolute Bias ±SD (b/min)	% Error	Bias	Mean Absolute Error
13.84±2.61	13.81±2.39	0.38±0.32	2.94	-0.03	0.38

\*No statistically significant difference in RR between RTM and Reference p=0.856

The RTMsense Respiratory Monitoring System met all clinical performance acceptance criteria, demonstrating correlation and agreement with manual ETCO<sub>2</sub> measurements. The lack of statistically significant difference in RR, along with low % error and mean absolute bias values, supports RTMsense’s substantial equivalence for acoustic respiratory monitoring.

### 8.0 CONCLUSION:

The results of the performance testing described above demonstrate that the RTMsense Respiratory Monitoring System is as safe and effective as the predicate device and supports a determination of substantial equivalence.