February 28, 2025

Heroic Faith International Ltd.
% Pierre Bounaud
Principal Consultant
Rqm+
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K242798
Trade/Device Name: Airmod
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: September 13, 2024
Received: September 16, 2024

Dear Pierre Bounaud:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachana Visaria -S

Rachana Visaria, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242798

Device Name
Airmod

Indications for Use *(Describe)*
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 of 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.

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.

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510(k) SUMMARY

DATE PREPARED
February 28, 2025

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Airmod™
Regulation Name:	Breathing frequency monitor
Regulation Number:	21 CFR 868.2375
Class:	II
Product Code:	BZQ
Premarket Review:	OHT1/ Division of Anesthesia, Respiratory, and Sleep Devices (DHT1C)
Review Panel:	Anesthesiology

PREDICATE DEVICE IDENTIFICATION
Airmod™ is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*	*Reference Device*
K111933	Covidien Nellcor Respiration Rate Software, Version 1.0 and Covidien Nellcor Adult Respiratory Sensor / Covidien	✓	
K120984	Masimo Acoustic Monitoring Sensors / Masimo Corporation		✓

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION
Airmod™ is an Android-based software application designed to aid healthcare professionals by monitoring a sedated and/or anesthetized patient's breathing in real time. The device has an AI-based algorithm that can detect inhalation acoustics and provides respiratory rates based on the analysis of the acoustic signals of breathing sounds collected by AccurSound Electronic Stethoscope AS-101. Airmod™ is intended for the continuous monitoring of respiratory rate (RR) in adults who are subjected to procedural sedation. Airmod™ is designed for use in hospitals and healthcare facilities performing procedural sedation/anesthesia. The device is not intended for patients who are not anesthetized/sedated.

INDICATIONS FOR USE

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 of 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Heroic Faith International believes that Airmod™ is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use and a similar design as the primary predicate device cleared in K111933, i.e., a software intended to be used with sensors as input to provide continuous, non-invasive monitoring of respiratory rates in a hospital setting. While the primary predicate was cleared as a system with specific sensors, the subject device is a software only device that is designed to accept sound files from a digital stethoscope as input.

The subject device has a different intended population than the primary predicate, i.e., it is intended for adults undergoing procedural sedation or anesthesia while the predicate is intended for adults in hospitals and hospital-type facilities. This intended population of the subject device is a subset of the intended population of the primary predicate and does not constitute a new intended use.

The subject device shares some technological characteristics with the primary predicate (K111933). Both are software with data from sensors as input and they both provide a respiratory rate measurement as output with a similar range and accuracy. The main differences in technological characteristics between the two devices are:

> **Principle of operation.** Airmod™ uses acoustic signals produced by the turbulent airflow in the upper airway that occurs during inhalation and exhalation for input. Those signals are recorded by microphones on a digital stethoscope. Signal processing algorithms then convert the acoustic patterns into breath cycles to calculate a respiratory rate. The primary predicate device uses pulse oximetry technology, sensors and workflows to derive respiration rate based on the changes in the photoplethysmogram waveform that occur as a result of breathing. Heroic Faith has conducted performance clinical testing to validate that the type of signals used by Airmod™ is compatible with the intended use of the device. Due to the similarities in technology (i.e., acoustic sensor, sensor application site), Masimo Acoustic Monitoring Sensors cleared in K120984 is used as a reference device to further support the use of acoustic signals for respiratory rate monitoring in a clinical setting.
>
> **Sensor application site.** The site of measurement on the patient is based on the mode of operation of the device. Since Airmod™ uses acoustic signals generated in the upper airway, the input sensor is placed on the patient's neck, while the primary predicate device has the sensor placed on the patient's finger to leverage pulse oximetry technology. Heroic Faith has conducted performance clinical testing to validate that the site of measurement used by Airmod™ is compatible with the intended use of the device. Due to the similarities in technology (i.e., acoustic sensor, sensor application site), Masimo Acoustic Monitoring Sensors cleared in K120984 is used as a reference device to further support the use of acoustic signals for respiratory rate monitoring in a clinical

setting.

Software interface/platform. Airmod™ is a software as medical device intended as a mobile application to be installed on compatible operating systems such as Android 10 and 11. Heroic Faith has conducted software V&V testing to validate Airmod™ as a mobile application for Android devices. Due to the similarities in technology (i.e., acoustic sensor, sensor application site), Masimo Acoustic Monitoring Sensors cleared in K120984 is used as a reference device to further support the use of acoustic signals for respiratory rate monitoring in a clinical setting.

A summary of the technological characteristics of the subject device and the predicate devices is presented in the table below.

	Subject Device	***Predicate Device***	***Reference Device***
	Airmod™	Covidien Nellcor Respiration Rate Software, Version 1.0 K111933	Masimo Acoustic Monitoring Sensors K120984
Indications for Use	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 of 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.	The Covidien Nellcor Respiration Rate Software, when used in conjunction with a Nellcor pulse oximeter and a Nellcor Respiration Rate Sensor, is intended to be used for the continuous, non-invasive monitoring of respiration rate in adults in hospitals and hospital-type facilities.	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.
Product Codes / Regulation Number	BZQ / 21 CFR 868.2375	• Primary: BZQ / 21 CFR 868.2375 • Secondary: DQA / 21 CFR 870.2700 • Secondary: DSA / 21 CFR 870.2900	• Primary: DQA / 21 CFR 870.2700 • Secondary: BZQ / 21 CFR 868.2375
Patient Population	Adults undergoing procedural sedation and/or anesthesia	Adults	Adults and pediatric
Use Environments	Hospitals and healthcare facilities	Hospital and hospital-like facilities	Hospitals, hospital-type facilities, mobile and home environments
Device Components	Software	• Hardware (sensors) • Software	• Hardware (sensors) • Software

Principle of Operation	Compatible stethoscope with microphone records acoustic signals produced by the turbulent airflow in the upper airway that occurs during inhalation and exhalation, while signal processing algorithms convert the acoustic patterns into breath cycles to calculate respiration rate	The Respiration Rate Software uses pulse oximetry technology, sensors and workflows to derive respiration rate based on the changes in the photoplethysmogram (pleth) waveform that occur as a result of breathing.	Sensor detects acoustic signals produced by the turbulent airflow in the upper airway that occurs during inhalation and exhalation, while signal processing algorithms convert the acoustic patterns into breath cycles to calculate respiration rate
Mode of Operation	Continuous monitoring	Continuous monitoring	Continuous monitoring
Sensor Application Site	Neck	Finger	Neck
Rate Measurement	Respiratory rate (RR) per min	Respiratory rate (RR) per min	Respiratory rate (RR) per min
RR Range and Accuracy	Clinical: 4-35 ±2.7 breath per min	Clinical: 4-40 ±1 breath per min	Benchtop: 4-70 ±1 breath per min Clinical: • Adult: up to 30 breath per minute • Pediatric: up to 50 breath per minute
Notifications/Alarms	User-adjustable notifications for RR lower/upper limits and speed of notifications (every 1 or 2 seconds)	User-adjustable alarms for RR lower/upper limits	Unknown
Software Interface/Display	Mobile device	Patient monitor	Patient monitor
Software Platform	Mobile application for Android 10 and 11 operating systems	Integrated software	Integrated software

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety and performance based on current industry standards:

- Software testing per IEC 62304 and FDA's guidance *Content of Premarket Submissions for Device Software Functions*.
- Cybersecurity testing per FDA's guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.*
- Bench performance testing, including validation of the active noise cancellation functionality.

SUMMARY OF CLINICAL TESTING

Clinical testing was conducted to evaluate the non-inferiority of Airmod™ compared to the Capnostream™35 capnography system during procedural sedation. The study included both outside of US (OUS) and US populations, totaling 270 participants across multiple healthcare facilities. Primary endpoints assessed the difference in respiratory rate measurements between Airmod™ (airRR) and manual scored capnography (mancRR) with a performance goal of Root Mean Square Error (RMSE) < 3 breaths per minute (BPM). Secondary endpoints examined performance during periods of abnormal end-tidal CO_2 graphs (ETF).

Summary Table for All Point Estimates (airRR-mancRR)

Test set	Mean Difference (95%CI)	Lower LOA (95%CI)	Upper LOA (95%CI)	RMSE (95% CI)
N=270	-0.457 (-0.519,-0.395)	-6.211 (-6.437,-5.994)	5.297 (5.105,5.501)	2.689 (2.529,2.695)

(95% CI based on bootstrap data)

Overall, Airmod™ demonstrated a mean difference of -0.457 breaths per minute (BPM) compared to mancRR (95% CI: -0.519 to -0.395). Additionally, the RMSE value for Airmod™ was found to be 2.689 BPM (CI: 2.529, 2.695) when compared to manCRR, thus meeting the primary outcome and demonstrating statistical equivalence to the reference device in the study. Bland-Altman analysis, concordance correlation coefficients, and measures of bias and precision further supported Airmod™'s performance.

CONCLUSION

Based on the testing performed, including software testing, cybersecurity testing, bench performance testing and clinical testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Airmod™ are assessed to be substantially equivalent to the predicate devices.