March 8, 2023

Respiree PTE Ltd.
% Cherita James
Regulatory Consultant
M Squared Associates, Inc
127 West 30th St. Floor 9
New York, New York 10001

Re: K223681
Trade/Device Name: Respiree Cardio-Respiratory Monitor
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: December 8, 2022
Received: December 8, 2022

Dear Cherita James:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223681

Device Name
Respiree Cardio-Respiratory Monitor

Indications for Use *(Describe)*
The Respiree Cardio-Respiratory Monitor is a respiratory monitor intended for hospitals and hospital-type facilities in non-ICU settings. The Respiree Cardio-Respiratory Monitor is indicated for the non-invasive spot checking of respiration rate (RR) for adult patients.

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.

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510(K) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for Respiree Cardio-Respiratory Monitor 510(k) premarket notification.

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Date Prepared: March 8, 2023

Trade/Device Name: Respiree Cardio-Respiratory Monitor
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Predicate Device(s): Primary – Philips IntelliVue CL Respiration Pod (K122223)
Reference - PneumaCare Thora-3Di, Model T-01 (K151940)

Device Description: The Respiree Cardio-Respiratory Monitor, Model RS001, is a small respiratory monitor. For measurement of respiration rate (RR), the device is affixed to the chest using a disposable adhesive patch with a hook-and-loop fastener to attach to the monitor. The device uses a vertical-cavity surface-emitting diode to emit optical radiation directed toward the skin. An integrated photodetector in a nearby position senses the diffused collected light. An adaptive signal processing method is used to enhance the device respiratory rate measurements by splitting the signal processing optimizations across different respiratory rate bands.

The monitor is powered by a 3.7V rechargeable, lithium-ion battery and a USB charging cable is provided. The Respiree Cardio-Respiratory Monitor also includes optional Bluetooth wireless technology for the wireless transfer of patient data to mobile devices.

Indication for Use: The Respiree Cardio-Respiratory Monitor is a respiratory monitor intended for hospitals and hospital-type facilities in non-ICU settings. The Respiree Cardio-Respiratory Monitor is indicated for the non-invasive spot checking of respiration rate (RR) for adult patients.

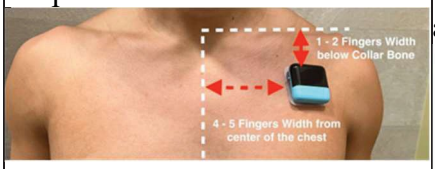
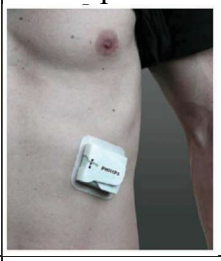
Substantial Equivalence

The claim of substantial equivalence of the Respiree Cardio-Respiratory Monitor to the primary predicate identified above is based on the comparison of the intended use, product technical characteristics, and performance characteristics. The Respiree Cardio-Respiratory Monitor is essentially a smaller, simplified version of the predicate device with similar technologic features to a reference device.

Comparison to the Predicate Device

	Respiree Cardio-Respiratory Monitor (Subject device)	**Philips Intellivue CL Respiration Pod (Primary Predicate)**	**Differences and SE**
510(k) No.	K223681	K122223	--
Primary Product Code	BZQ	BZQ	Same
Intended Use/Indications for Use	The Respiree Cardio-Respiratory Monitor is a respiratory monitor intended for hospitals and hospital-type facilities in non-ICU settings. The Respiree Cardio-Respiratory Monitor is indicated for the non-invasive spot checking of respiration rate (RR) for adult patients.	The IntelliVue CL Respiration Pod is indicated for use by health care professionals whenever there is a need for intermittent or spot-check acquisition and monitoring of physiological patient parameters respiration rate and pulse rate wirelessly in specific hospital areas. The IntelliVue CL Respiration Pod is mainly indicated for use in general medical and surgery wards and in waiting areas of emergency rooms. It is not indicated for use in hospital areas in which continuous patient monitoring is needed, such as intensive care units or operating rooms. The intended use of the IntelliVue CL Respiration Pod when used together with a patient monitor is for intermittent or spot-check monitoring and recording of, and to generate	Similar. Minor text difference does not suggest a new or different intended use/ indication for use. There is no change to the use, users or conditions of use. Both devices measure respiration rate in adults for spot check monitoring. Both devices are indicated for use by healthcare professional in hospital settings.

		alarms for respiration rate and pulse rate of adult patients. The IntelliVue CL Respiration Pod is also intended for acquisition of respiration rate and pulse rate data of adult patients for a clinical information management system. The Intellivue CL Respiration Pod is intended for use by health care professionals. It is not intended for home use. It is not a therapeutic device. The IntelliVue CL Respiration Pod is not intended for use on patients with extremely high values for respiration rate (above 60 rpm). The IntelliVue CL Respiration Pod is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias, e.g. very fast atrial fibrillation or ventricular tachycardia (rapid irregular pulse rate). For monitoring of these patients, a device for continuous ECG monitoring is necessary. The IntelliVue CL Respiration Pod is not a substitute for an ECG monitor.	

	Respiree Cardio-Respiratory Monitor	**Philips Intellivue CL Respiration Pod**	**Differences and SE**
Measurement Principle	Uses optical sensor to measure thoracic movements.	Uses accelerometer sensor to measure thoracic movements.	Similar technology method. Sensor technology of subject device is different from predicate but is similar to reference device.
Patient interface	Sensor is adhesively attached to the patient's chest 	Pod is adhesively attached to left costal arch of patient's chest 	Same. Sensor is attached to the patient's chest.
Environment of Use	Hospital and hospital-type environment only (non-ICU settings)	Hospital	Same
Target population	Adult only	Adult only	Same
Displayed parameters	Respiration rate is shown on the Cardio- respiration monitor display. Retrospective data can be viewed and/or downloaded from Respiree Health App	Respiration data is sent to an assigned compatible intelliVue Patient Monitor or IntelliVue Guardian Software.	Difference in the way the data is displayed does not raise new questions of safety and effectiveness.
Mode of operation	Spot checking	Intermittent or spot-check	Same
Performance range	5 – 50 rpm	5 – 60 bpm	Similar. Performance and clinical study confirm the essential performance of the device at the extremes of the stated performance range.
Performance accuracy (ARMS)	<3 rpm	<2 rpm	Similar. Clinical study demonstrates respiration rate accuracy.
Alarms	None	Yes	Difference do not raise new questions of safety and effectiveness. The subject device is only intended for spot

			monitoring of respiration rate.
Power Supply	Rechargeable Lithium- ion battery	Rechargeable Lithium-ion battery	Same
Wireless Interface	Bluetooth LE	Short Range Radio	Similar principle of operation
Biocompatibility	Complies with ISO 10993-1, ISO 10993-5, and ISO 10993-10	Not available	Adhesive patch used in subject device is biocompatible.
Safety and EMC Specifications	AAMI IEC ES 60601-1:2005, IEC 60601-1-2: 2020, ANSI IEEE 63.27-2017	AAMI ANSI ES 60601-1:2005, IEC 60601-1-2:2007 IEC 60601-1-8:2006	Same. Subject device complies with current versions of the applicable standards.
Dimensions	40 mm x 40 mm x 13 mm	Pod: 45 mm x 14 mm x 65 mm ±5% (without accessories)	Similar.

The subject device and the Primary Predicate (K122223) have the following key similarities:

- Both devices have similar intended and indications for use.
- Both devices measure respiration rate as spot monitoring.
- Both devices measure respiration rate from the chest and are patient contacting.
- Both devices use the similar technology method of looking at signals generated from chest wall or thoracic movement to assess respiration rate.
- Both devices have similar performance range (Predicate is 5 – 60 rpm, subject device is 5 – 50 rpm) and performance accuracy (Predicate is <2 rpm, subject device is <3 rpm)
- Both devices use BZQ primary product code.

The subject device and the Primary Predicate (K122223) have the following key difference:

- The subject device uses optical sensor for respiration rate measurement whereas the primary predicate uses an accelerometer sensor.

Comparison to reference device

- A reference device was used to further support the sensor technology of the subject device for respiration rate measurement.

	Respiree Cardio-Respiratory Monitor (Subject)	**PneumaCare Thora-3Di Model T-01 (Reference)**	**Differences and SE**
510(k) No.	K223681	K151940	-
Product Code	BZQ	BZQ	Same

Intended Use/Indications for Use	The Respiree Cardio-Respiratory Monitor is a respiratory monitor intended for hospitals and hospital-type facilities in non- ICU settings. The Respiree Cardio-Respiratory Monitor is indicated for the non-invasive spot checking of respiration rate (RR) for adult patients.	The Thora-3Di is intended for a one-time measurement of respiratory rate as part of a vital signs assessment. The device is indicated for hospital or clinical use in adult patients. The device is intended to be operated by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider. The Thora- 3Di is not intended to monitor vital signs. This device is not an apnea monitor.	Both devices measure respiration rate in adults. While the subject device is intended for spot check monitoring, the reference device is intended for one-time measurement. Both devices are indicated for use by healthcare professional in hospital settings. As a reference device, this difference does not impact safety/effectiveness, as both subject and primary predicate are SE for spot-checking.
Sensor Technology and measurement	Uses optical sensor to measure thoracic movements.	Uses optical sensor to measure thoracic movements.	The reference device uses visual technique using cameras and a projector to look at chest and abdominal wall movement, while the subject device captures thoracic movement emitting optical radiation and intensity changes at the skin are captured by an integrated photodetector. Both methods are evaluating signals generated from chest wall displacement to assess respiratory rate.
Intended Application Site	Chest (direct contact)	Chest (non-contact)	As a reference device, this difference does not impact safety/effectiveness, as both subject and primary predicate are chest contacting.

The reference device is similar to the subject device as follows:

- Same application site for respiration rate measurement on the chest
- Same technology for respiration rate measurement using optical technology

The reference device only differs from the subject device by the fact that the reference device is a non-contact approach versus the subject device that is a contact approach.

Performance Data

- Device conforms to software requirements for Moderate Level of Concern devices in accordance with FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- Device conforms to FDA's Cybersecurity Guidance on Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Device conforms to FDA's guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Patient contacting components were found to be biocompatible in accordance with ISO 10993-1, -5 and -10 for prolonged contact with intact skin.
- Human factors and usability testing was conducted by intended users to support the acceptability of the human factors and usability risks associated with clinical use.
- Other testing included bench testing of Respiratory Rate, Adhesive Patch Peal Force, and Bluetooth.

Conformity to Standards

Respiree Cardio-Respiratory Monitor has been tested and meets the requirements of the relevant sections of the following performance standards:

Standard	Recognition Number
ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-258
ISO 10993-5, 2009, Biological Evaluation of Medical Devices - Part 5: Test for In Vitro Cytotoxicity	2-245
ISO 10993-10, 2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization	2-174
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	19-4
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	19-36

IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89
IEC 62366-1 Edition 1.1 2020-06 Consolidated Version Medical devices – Part 1: Application of usability engineering to medical devices	5-129
Title 47 Telecommunication, Part 15 Code of Federal Regulations- Radio Frequency Devices	N/A
Title 47 Telecommunication, Part 18 Code of Federal Regulations- Industrial, Scientific, and Medical Equipment	N/A
ISO 14971:2019 Medical devices - Application of risk management to medical devices.	5-125
UL 1642 Standard for Lithium Batteries	19-10
ANSI IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence	19-29

Clinical Data

Clinical validation of the Respiree Cardio-respiratory Monitor was performed for respiratory rate. Respiree Cardio-respiratory Monitor was benchmarked to Reference $EtCO_2$ waveform (from Datex-Ohmeda) that was manually scored by counting the respiratory peaks per minute on a total of 46 subjects. The clinical validation was conducted to demonstrate that the Respiree Cardio- respiratory Monitor performs adequately for all groups within the intended population. The study had a wide, well-distributed range of comorbidities, age (20-80 years), race (white, black and others), BMI (19.1-45.2) and skin tone (Fitzpatrick skin tone type II-VI), as well as a balanced mix of gender (50% male).

Effectiveness:

The clinical studies demonstrated Respiree Cardio- respiratory Monitor met the respiratory rate accuracy A_{rms} of <3 rpm when compared to the reference $EtCO_2$ waveform that is scored by counting the respiratory peaks per minute.

Safety:

There is no adverse event and complication observed in the clinical studies.

Summary:

Based on the clinical performance, Respiree Cardio-respiratory system is found to have a safety and effectiveness profile that is similar to the predicate device.

Conclusion

Respiree Cardio-respiratory Monitor has similar intended use and indications statements, fundamental technology as the predicate device for the measurement of respiratory rate. The differences do not raise new questions of safety and effectiveness.

Performance testing, clinical data and conformity to standards confirm that the device performs as intended. Therefore, the Respiree Cardio-respiratory Monitor is substantially equivalent to the predicate device.