October 7, 2022

PMD Solutions
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K220111
Trade/Device Name: RespiraSense
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BQZ
Dated: August 30, 2022
Received: August 30, 2022

Dear Paul Dryden:

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, 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

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)*
K220111

Device Name
RespiraSense

Indications for Use *(Describe)*
The RespiraSense is indicated for continuous, non-invasive, and real-time monitoring of respiratory rate. RespiraSense is indicated for patients 18 years and older in hospitals, hospital-type facilities and while patients are mobile (e.g., walking). RespiraSense is not intended to be an apnoea monitor.

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

PMD Solutions RespiraSense

Date Summary was prepared: October 6, 2022

I. SPONSOR

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Sponsor Contact: Myles Murray – President

Submission Correspondent: Paul Dryden
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II. DEVICE

Name of the device:	RespiraSense
Common Name:	Breathing Frequency Monitor
Classification CFR:	21 CFR 868.2375
Classification Name:	Monitor, Breathing Frequency
Product Code:	BZQ

III. PREDICATE DEVICE AND REFERENCE DEVICE

Predicate Device:	Philips Intellivue CL Respiration Pod (K122223)
Common/Usual Name:	Breathing Frequency Monitor
Classification CFR:	21 CFR 868.2375
Classification Code:	BZQ / DRG / MSX
Classification Name:	Monitor, Breathing Frequency / Transmitters and Receivers, Physiological Signal, Radio Frequency / System, Network and Communication, Physiological Monitors

Reference Device:	Masimo Rainbow SET Acoustic Monitoring sensor (K120984)
Common/Usual Name:	Oximeter
Classification CFR:	21 CFR 870.2700
Classification Name:	Oximeter / Monitor, Breathing Frequency
Product Code:	DQA / BZQ

IV. DEVICE DESCRIPTION

The RespiraSense (RS) monitors respiratory rate by directly measuring displacements of the chest and abdomen that occur during breathing which are analogous of respiratory rate. This is measured using piezoelectric film elements that output a varying voltage when displaced.

The RS device is a non-invasive, wireless, respiratory rate (RR) monitor that is worn on the body of the patient. It is internally-powered, and enables continuous RR monitoring from a single application for up to four days. It is designed to enhance the ability of medical staff to reliably measure respiratory rate remotely.

The RS Device is comprised of the RespiraSense Lobe (hereafter the Lobe), the reusable component that houses the RS Device's electronics, a single use adhesive RespiraSense Sensor (hereafter the Sensor) and Cradle. The Lobe and Sensor connect via a secured flat cable and are mechanically fastened together using a plastic Cradle. The Lobe and Sensor are placed on the left-hand side of a patient's torso.

The Lobe transmits wirelessly via Bluetooth to an iPad running PMDs RS App for display, control and alert functionality. The RS App allows for

- Configuring the Lobe
- Displaying respiration rate
- Display SpO2 and Pulse rate from a connected Nonin device (optional)
- Configuring alert limits

The RS application can also connect to and display information from multiple Lobes simultaneously.

The Lobe is rechargeable. It is designed to be charged using the supplied Charging Station. Charging must be done outside of the immediate patient environment. Charging cannot occur while the device is in operation. Up to six Lobes can be charged at one time.

The Sensor is the only patient-contacting device and is secured to the patient with medical grade adhesive.

V. INDICATIONS FOR USE

The RespiraSense is indicated for continuous, non-invasive, and real-time monitoring of respiratory rate. RespiraSense is indicated for patients 18 years and older in hospitals, hospital-type facilities and while patients are mobile (e.g., walking). RespiraSense is not intended to be an apnoea monitor.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE AND REFERENCE DEVICE

The table below outlines the features of the RespiraSense Respiratory Rate Monitor and compares it to the predicate devices to establish substantial equivalence.

Parameter	**Subject Device RespiraSense (K220111)**	**Predicate Device Philips Intellivue CL Respiration Pod (K122223)**	**Reference Device Masimo Rainbow SET Acoustic Monitoring sensor (K120984)**	**Comparison**
Classification Name	Breathing Frequency Monitor	Breathing Frequency Monitor	Breathing Frequency Monitor	Similar
Indications for Use	The RespiraSense is indicated for continuous, non-invasive, and real-time monitoring of respiratory rate. RespiraSense is indicated for patients 18 years and older in hospitals, hospital-type facilities and while patients are mobile (e.g., walking). RespiraSense is not intended to be an apnoea monitor.	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 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.	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.	Similar to both predicate and reference for measuring respiratory rate in the intended population and environment.

Parameter	**Subject Device RespiraSense (K220111)**	**Predicate Device Philips Intellivue CL Respiration Pod (K122223)**	**Reference Device Masimo Rainbow SET Acoustic Monitoring sensor (K120984)**	**Comparison**
Measurement Principle	Thoracic and abdominal movements from respiratory effort. Bending of the piezo sensor caused by chest and abdomen movements during breathing produce a voltage signal, from which respiration rate is derived. Integrated accelerometer provides means to correct artefacts.	Thoracic movements from respiratory effort - Inclination changes of the incorporated accelerometer sensor, caused by chest and abdomen movements during breathing and heart contraction, produce a voltage signal, from which respiration and pulse rate signals are derived.	Use of piezoelectric sensor element for the purpose of non-invasive respiratory rate monitoring. As air flows, the acoustic vibrations are measured by the sensors and processed to determined respiratory rate.	Similar principle of operations, sensor technology of subject device is different from predicate but similar to reference device.
Patient Interface	Lobe attached to sensor. Sensor adhesively attached to patient's chest.	Pod attached to strap. Strap adhesively attached to patient.	Sensor adhered to the neck of the patient, close to the windpipe. A cable connects the sensor to a nearby monitor.	Similar
Patient Population	Patients aged 18 or over	Adult	Adult and pediatric patients	Similar
Prescriptive	Yes	Yes	Yes	Similar
Environment	Hospital, hospital-type facilities, and mobile	Hospital	Hospitals, hospital-type facilities, mobile and home environments.	Similar
Hardware	Small body-worn device with adhesive attachment, data is sent to the RespiraSense Software Application. Lobe hardware consists of a battery and an electronic module with the embedded processor, accelerometer, dsPIC microcontroller, Bluetooth Low Energy (BLE) transceiver, Sounder and LED. Encased in a plastic housing.	Small body-worn pod with adhesive attachment, data is sent to an assigned compatible IntelliVue Patient Monitor or IntelliVue Guardian Software. Pod hardware consists of a battery and an electronic module with the embedded processor, accelerometer, SRR transceiver and speaker. Encased in a plastic housing.	A small piezoelectric sensor strip adhered to the neck of the patient and connected via a Masimo RD cables from the sensor to a peripheral bedside patient monitor.	Similar
Software	The RespiraSense Lobe provides and communicates measurement values and other information (e.g., battery state) wirelessly as encrypted data via an encrypted BLE wireless protocol to the RespiraSense Software Application on a iPad. The RespiraSense Application manages bidirectional communication between Lobe and the RespiraSense Application installed on a COTS Tablet Computer	The CL Respiration Pod provides and communicates measurements values and other information (e.g., battery state) wirelessly via Short Range Radio (SRR) to an assigned compatible IntelliVue Patient Monitor or IntelliVue Guardian Software. The CL Respiration Pod can be controlled from the assigned IntelliVue Patient Monitor or IntelliVue Guardian Software run on PC or server.	All software is managed by the peripheral bedside patient monitor to which the sensor is connected to. The Bedside patient monitor provides power to the sensor.	Similar

Parameter	**Subject Device RespiraSense (K220111)**	**Predicate Device Philips Intellivue CL Respiration Pod (K122223)**	**Reference Device Masimo Rainbow SET Acoustic Monitoring sensor (K120984)**	**Comparison**
Performance Specification	Range: 6 - 60 breaths per minute Resolution: 1 breath per minute Accuracy: ±3 breaths per minute	Range: 5 – 60 breaths per minute Resolution: 1 breath per minute Accuracy: ±1 breath per minute	Range: 4-70 breaths per minute Resolution: 1 breath per minute Accuracy ±1 breaths per minute	Difference on the lower range of respiration has no impact on safety or efficacy. For accuracy there is reference Biobeat K212153 which has BPM accuracy of ±3 bpm to support equivalence.
Wireless Connectivity	Bluetooth 4.2	Short Range Radio	N/A	Similar principle of operation
Power Source	Rechargeable Lithium-Ion battery	Rechargeable Lithium-Ion battery	Peripheral Bedside Monitor	Similar
Patient contacting parts	Adhesive attaching device to patient's chest.	Adhesive attaching device to patient's chest.	Adhesive attaching device to the patient's neck.	Similar
Safety and EMC Standards	AAMI ANSI ES 60601-1 :2015 +A1:2012 IEC 60601-1-2:2014 IEC 60601-1-8:2012 ANSI 63.27-2017 AIM 735173	AAMI ANSI ES 60601-1:2005 IEC 60601-1-2:2007 IEC 60601-1-8:2006	IEC 60601-1 IEC 60601-1-2	Subject device complies with the current versions of the applicable standards.
Dimensions	57 mm x 98 mm x 18 mm (without sensor)	Pod: 53.5 mm x 27 mm x 65 mm ±5% (2.1 in x 1.1 in x 2.6 in ±5%) (without cradle and sensor)	Sensor: 135 mm x 22mm x 3 mm accompanied by a 3-3.5m cable	Similar
Weight	57 g	80 g ±10% (2.8 oz ±10%)	<20g (excluding cable)	Similar

VII. PERFORMANCE DATA:

Bench testing – Bench testing was performed that includes:

- Shelf-life / Aging
- Software Verification and Validation - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- AAMI ANSI ES 60601-1:2015+A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Collateral standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-8 2012 Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ANSI IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence
- AIM 7351731 Rev. 2.00 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
- Cybersecurity Content of Premarket Submissions for Management of Cybersecurity in Medical devices

Discussion – The subject device meets the applicable standards similar to the predicate device.

Biocompatibility – The adhesive of the sensor is applied to intact skin with a prolonged duration (up to 4 days). Testing was performed per:

- ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization

Discussion – Both devices use single-use disposable biocompatible adhesive compliant with applicable parts of the ISO 10993-1 Biological Evaluation standard to adhere to intact skin.

Clinical Testing

We performed a multi-site comparative clinical testing in the intended population and the environment comparing the subject device to the gold standard EtCO2. A total of 56 subjects were evaluated by manual counting and / or comparison to a FDA cleared end-tidal CO2 monitor with the observer blinded to the EtCO2 monitor. The subject covered the age range of > 18 years old and split by gender. The statistical analysis showed that the subject device are substantially equivalent to the gold standard of $\pm$ 3 bpm at a 95% confidence level. The results supported the claims of substantial equivalence for the intended use.

VIII. CONCLUSION:

The testing performed and comparison to the predicate demonstrate that the subject device is substantially equivalent to the predicate.