October 18, 2019

Respironics Inc.
Amy Panzik
Regulatory Affairs Project Manager
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K183625
Trade/Device Name: SomnaPatch
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: September 18, 2019
Received: September 20, 2019

Dear Amy Panzik:

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,

for

Michael Ryan
Division Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183625

Device Name
SomnaPatch™

Indications for Use *(Describe)*
The SomnaPatch™ is a single use physiologic recorder intended to collect and record data for use by clinical software used in polysomnography and sleep disorder studies by providing the information required for calculation of the apnea-hypopnea index. It is intended for adult use and can be used in a hospital, clinic, or patient home.

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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Submitter

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Date of Preparation October 16, 2019

Device

Proprietary Name: SomnaPatch™

Common/Usual Name: Ventilatory Effort Recorder

Device Classification: 21 CFR 868.2375 - Class II

Classification Name/ Product Code: MNR, Ventilatory Effort Recorder

Primary Predicate Device: Alice PDx (K090484)

Device Description

The SomnaPatch Home Sleep Test is a single-use disposable physiologic recorder used as an aid in the diagnosis of sleep related breathing disorders. The SomnaPatch device is affixed to the face of the user and is designed to continuously be worn overnight, up to approximately 10-hours. Once activated, the device records and stores patient data for the duration of the wear period. After the wear period, the device is returned to the healthcare professional, where the data is downloaded and processed by the SomnaPatch Data Processing Software. The processed data can be viewed by a healthcare professional and analyzed either manually or by third-party sleep data viewing and scoring software. The SomnaPatch device is not involved in the data management performed by the host or third-party data viewing or scoring software.

The forehead patch contains three sensors (Pressure Sensor, Accelerometer, and Optical SpO_2), wherein their outputs' are recorded to a secure MicroSD card. The SomnaPatch Data Processing Software installed on a PC downloads the recorded data from the secure MicroSD card to derive 4 channels (nasal pressure, oxygen saturation (SpO_2), pulse rate, and head position) of data in EDF format.

Indications for Use

The SomnaPatch™ is a single use physiologic recorder intended to collect and record data for use by clinical software used in polysomnography and sleep disorder studies by providing the information required for calculation of the apnea-hypopnea index. It is intended for adult use and can be used in a hospital, clinic, or patient home.

Comparison of Technological Characteristics with the Predicate Device

The SomnaPatch Home Sleep Test is similar to the predicate device, Alice PDx (K090484). The SomnaPatch device has a similar intended use, operating principles, similar technological characteristics, collection of physiological signals, and wearable simultaneous patient recording capability. Table 5-1 below, provides a comparison of the technological characteristics with the predicate device and SomnaPatch.

Table 5-1: Comparison of the Technological Characteristics with the Predicate Device

Characteristic	Respironics Alice PDx	SomnaPatch™
510k	K090484	K183625
Manufacturer	Respironics Inc.	Respironics Inc.
Device Classification	Class II	Unchanged from K090484
FDA Product Code	MNR 21 CFR 868.2375	Unchanged from K090484
Intended Use	The Alice PDx is a physiological data recorder intended to collect and record data from multiple physiological channels for use by clinical software used in polysomnography and sleep disorder studies.	Unchanged from K090484
Indications for Use	The Alice PDx is a physiological data recorder intended to collect and record data from multiple physiological channels for use by clinical software used in polysomnography and sleep disorder studies. It is intended for use by or on the order of a physician. It is intended for use on adults in a supervised (hospital) or unsupervised (home) environment.	The SomnaPatch™ is a single use physiologic recorder intended to collect and record data for use by clinical software used in polysomnography and sleep disorder studies by providing the information required for calculation of the apnea-hypopnea index. It is intended for adult use and can be used in a hospital, clinic, or patient home.
Prescribed	Prescription Only	Unchanged from K090484
Target Population	Adults	Unchanged from K090484
Environment of Use	Home or Hospital	Unchanged from K090484
Device Type	Ventilatory Effort Recorder	Unchanged from K090484
Principle of Operation	• Microprocessor controlled • Electronically Powered • Software Driven	Unchanged from K090484

Simultaneous Patient Recording Capability	1 patient per unit	Unchanged from K090484
Sensors/Wearable	Nasal Cannula, chest and abdominal effort belts, finger SpO_2 sensor	Nasal Cannula, forehead Optical SpO_2 sensor, Accelerometer, Pressure Sensor
Portability	Wearable	Unchanged from K090484
Patient Usage Type	Reusable, multi-patient use, Data Recorder	Disposable, Single-Use, Data Recorder
Sterility Condition	Device provided clean, but not sterile	Unchanged from K090484
Connectivity	1 serial interface • Connect Alice PDx to the host PC running the host software, or • Connect Alice PDx to a Therapy Device	No serial interface connection.
Device Alarms	None	Unchanged from K090484

Data Input Types	ECG, Neurological, Respiratory	Respiratory

Number of Channels	20 Channels
	• Nasal Pressure/Oral (Nasal Cannula (K982293)) x1
	  o Nasal Pressure (Thermistor) x1
	• Pulse Oximetry
	  o Oxygen Saturation – SpO_2 x1
	  o Pulse Rate x1
	  o Plethysmograph x1
	• Thoracic x1 and Abdominal Effort x1
	• Body Position x1
	• EEG/EOG x4, EMG x3, ECG x4 (optional)
	• Snore x1
		4 Channels
		• Nasal Pressure (Nasal Cannula (K982293)) x1
		• Pulse Oximetry
		  o Oxygen Saturation- SpO_2 (PhotoSensor) x1
		  o Pulse Rate (PhotoSensor) x1
		• Head Position (Accelerometer) x1
		
		SomnaPatch when compared with Alice PDx has a reduction of channels. This does not affect the safety and efficacy of the device, as demonstrated by the clinical trial.

Sensor Technology	Analog pressure transducer, transmissive optical sensor, accelerometer, ProTech zRIP respiratory effort sensor (K013905)	Digital pressure transducer with on-chip calibration, reflective optical sensor, accelerometer
Data Collection	Yes, data recorder collects and records physiological data from sensors placed on the patient's body.	Unchanged from K090484
Data Storage	Data stored on removable secure digital (SD) Card	Unchanged from K090484
Data Analysis	No data analysis provided by the recorder. FDA cleared software applications may be used. The FDA cleared host software application is Sleepware (K040595)	Unchanged from K090484
Report Generation	No report generation provided by the recorder. FDA cleared host software applications may be used.	Unchanged from K090484

Recording Capacity	~18 Hours - Continuous Use	~10 Hours Continuous Use
Dimension	5” L x 3”W x 2” H (12.7 cm x 7.62 cm x 5.08 cm) Approximately 8 oz (230 grams) (weight does not include batteries)	2.65” L x 1.875” W x 0.500” H (6.7 cm x 4.8 cm x 1.3 cm) Approximately 0.6 oz (17 grams with batteries)
Energy Source	Battery Powered 3, 1.5V, AA-size Alkaline batteries	Battery Powered 2, Coin Cell batteries, Li/MnO2, Model CR-2430
Materials/Biocompatibility	Per ISO 10993	Materials used to comprise the SomnaPatch device are different than those used with the predicate device. The new materials are identified in the Biocompatibility Section (Section 15). These materials have been biologically assessed per ISO 10993 and deemed safe for use in the SomnaPatch device.

Clinical Tests

A multi-center, open label study, within-subject comparison of 178 participants with a wide range of sleep-disordered breathing severity, as determined by a PSG-AHI range 0.1 to 147.7 events/hour, was conducted for the SomnaPatch device to evaluate the AHI accuracy as compared with the gold standard, overnight polysomnography (PSG) during laboratory recording. The mean difference in the AHI was -0.7 events per hour (95% confidence interval -2.4 to 1.1 events/hour). The results of this study demonstrate that the SomnaPatch device accurately estimates the AHI for values >=15 events/hour as compared with in-lab polysomnography (PSG).

In addition, Respironics partnered with a third-party study site, the University of California San Francisco (UCSF) Hypoxia Research Laboratory, to complete clinical testing to validate the SpO_2 signal of the SomnaPatch device. Our 510(k) submission (K183625) includes data to support the accuracy of the SomnaPatch SpO_2 signal against arterial blood samples drawn under hypoxic conditions over the SaO_2 range of 70-100%. The oximeter performs within the standard accuracy range of ±4% for non-invasive pulse oximetry, the same as compared to Alice PDx.

Performance Data- Non-Clinical Tests

Software verification and validation testing

Software verification and validation testing was performed on the SomnaPatch Firmware and SomnaPatch Data Processing Software based on the product requirements. Testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", for Minor Software Level of Concern.

This testing included complete system level testing to verify all required functionality of the SomnaPatch device.

SomnaPatch Sensors

Comparative performance testing was conducted for all three SomnaPatch sensors (Optical SpO_2, Accelerometer, and Pressure Sensor). Performance testing was completed on the SomnaPatch Optical SpO2 sensor and the Alice PDx compatible Nonin Transmittance and Reflective pulse oximeters. The testing of the sensors was conducted on a patient simulator specific to reflective pulse oximeter sensors. The output of the data from both the subject and predicate devices were compared. As a result, the performance of the SomnaPatch device was comparable to the Nonin pulse oximeters and was in agreeance with the expected pulse rate, as shown in the test report.

The Alice PDx accelerometer was compared to the SomnaPatch accelerometer to ensure both devices present comparable position data to the healthcare professional. The testing was conducted with the accelerometers lying on a flat surface changing position every 1-20 seconds. All motion from both accelerometers recorded as intended. The SomnaPatch accelerometer performed comparable to the Alice PDx accelerometer, as show in the full test report.

Lastly, performance testing was conducted to compare the data captured by the SomnaPatch device's pressure sensor to the data captured from the Alice PDx pressure-based flow output. Hypopneas, apneas, and nominal breaths were generated using ASL scripts. The SomnaPatch and Alice PDx recorded this data; the data was then loaded into Sleepware G3 to view the hypopneas

and apneas. The percentage of reduction in waveform was calculated for both the hypopnea and the apnea based on the nominal breath. As a result, the SomnaPatch pressure sensor data and Alice PDx pressure-based flow were able to detect hypopneas and apneas generated by the ASL, as provided in the complete test report.

Based on the comparative performance analysis of the three sensors from the SomnaPatch device compared to the sensors of Alice PDx, all performed comparatively ensuring that the measured data from each sensor does not provide erroneous results and remains substantial equivalent.

Biocompatibility Testing

The biocompatibility evaluation for the SomnaPatch device was conducted in accordance with FDA Guidance, “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA. All device components were tested in their final, finished, form and were production equivalent. SomnaPatch makes limited duration (< 24 h) skin contact with the patient when used as intended, with the nasal cannula making limited duration mucosal membrane contact. Due to the classification of the SomnaPatch device a variety of biological endpoints were evaluated and the testing performed indicates that the production equivalent device showed no potential for cytotoxicity and sensitization and negligible irritation results. Acute systemic toxicity results revealed no evidence of mortality or toxicity. As a result, the SomnaPatch device is considered biocompatible and presents no foreseeable increased biological risk to the patient population it is intended for.

Biological endpoint	ISO Standard
Cytotoxicity	10993-5:2009
Sensitization	10993-10:2010
Irritation	10993-10:2010
Systemic Toxicity (Acute)	10993-11:2017

Risk Assessment

A Risk Assessment has been prepared for the SomnaPatch device in accordance with ISO 14971:2007, *Medical Devices- Applications of Risk Management to Medical Devices.* This Risk Assessment assess possible hazards associated with the use of this product relative to the intended patient population and use environment. It identifies hazards and control measure used to mitigate relevant hazards to reduce risk.

General Safety, Electrical Safety and Electromagnetic Compatibility (EMC)

General Safety, Electrical safety and EMC testing were conducted on the SomnaPatch device. The system complies with the following standards:

- IEC 60601-1:2005/A1:2012
- IEC 60601-1-2:2007
- IEC 60601-1-6:2013
- IEC 60601-1-11:2015
- ISO 80601-2-61: 2011

The testing of the SomnaPatch device verified that all product requirements have been met with passing test results. The verification and validation testing demonstrated comparable safety and effectiveness of SomnaPatch to the predicates.

Substantial Equivalence

This premarket notification submission demonstrates that the SomnaPatch Home Sleep Test is substantially equivalent to the Respironics Alice PDx (K090484) device. The functionality of the design of the device was verified through a clinical trial and verification testing. Based on the comparative performance analysis of the three sensors (Optical SpO_2, Pressure, and Accelerometer) from the SomnaPatch device compared to the sensors of Alice PDx, all performed comparatively ensuring that the measured data from each sensor does not provide erroneous results and remains substantial equivalent. The clinical study was undertaken to determine the level of agreement between the SomnaPatch-AHI and the PSG-AHI. As a result, the SomnaPatch provides the information required to generate the AHI for evaluation of moderate to severe sleep-disordered breathing. No new concerns of safety and effectiveness have been raised. It is therefore concluded that the SomnaPatch Home Sleep Test is substantially equivalent to the predicate device, Respironics Alice PDx (K090484).