K131932

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510(k) Summary

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Date prepared	4th October 2013
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Classification Reference	21 CFR 868.2375
Product Code	MNR – Ventilatory Effort Recorder
Common/Usual Name	Ventilatory Effort Recorder
Proprietary Name	ApneaLink Pro
Predicate Device	ApneaLink Plus (K083575)
Reason for submission	New device

Device Description

The ApneaLink Pro recorder is the successor model of the previously cleared ApneaLink Plus (K083575). The new development was required due to design changes and as various components of the ApneaLink Plus won't be available any longer.

The ApneaLink Pro recorder is a 4-channel battery-powered respiratory pressure sensor and oximetry system. ApneaLink Pro provides recordings of respiratory pressure, respiratory effort, pulse rate and oxygen saturation during sleep. The physician prescribed device will help to recognize sleep-related respiratory disorders. The patient may perform the recording at home by himself. The ApneaLink Pro recorder and the respiratory effort sensor must be fastened with the re-usable belt on the patient's chest. All relevant respiratory information during sleep will be collected via nasal cannula, pulse oximetry module and respiratory effort sensor. The disposable plastic nasal cannula is connected to the ApneaLink Pro recorder and fixed at the patient's nose. The oximetry sensor is connected to the Xpod and fixed at the patient's finger. The Xpod is connected to the ApneaLink Pro recorder. The respiratory effort sensor is connected to the ApneaLink Pro recorder and held in place by the belt. LED's indicate if the sensors are attached correctly. A *Test complete* light advises at the end of a recording if sufficient data for analysis was recorded during the night. After recording, the ApneaLink Pro recorder must be returned to the physician. With the ApneaLink Software installed on a personal computer the physician can generate a report with the recorded and analyzed data to aid in diagnosis. The recordings and the report can be sent via email to further clinical investigation.

Note: The ApneaLink Pro is prepared to support actigraphy in future versions of the device. In the current version which is object of this submission the feature is not activated and can't be activated by the user.

Intended Use

The ApneaLink™ Pro device is indicated for use by Health Care Professionals (HCP), where it may aid in the diagnosis of sleep disordered breathing for adult patients. ApneaLink Pro records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse and respiratory effort during sleep. The device uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing or for further clinical investigation. The device is intended for home and hospital use under the direction of a HCP.

Technology

The ApneaLink Pro is different from the predicate device ApneaLink Plus (K083575) with respect to:

- Display operation
  - More user friendly display (Test Complete Indicator LED; Sensor LEDs , Start/Stop LED)
- Microprocessor
  - New microcontroller with technology regarding interfaces and USB driver
- Communication between embedded software and PC application
  - Data is stored in EDF+ files instead of proprietary data format file. Additionally device serves as mass storage device

Substantial Equivalence

The table below provides an abbreviated summary of the primary relevant characteristics of ApneaLink Pro compared to the predicate device.

CHARACTERISTIC	PREDICATE **ApneaLink Plus** (K083575)	NEW DEVICE **ApneaLink Pro**	COMMENTS **ApneaLink Plus vs. ApneaLink Pro**
Intended Use	The ApneaLink™ Plus device is indicated for use by Health Care Professionals (HCP), where it may aid in the diagnosis of sleep disordered breathing for adult patients. ApneaLink Plus records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse and respiratory effort during sleep. The device uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing or for further clinical investigation.	The ApneaLink™ Pro device is indicated for use by Health Care Professionals (HCP), where it may aid in the diagnosis of sleep disordered breathing for adult patients. ApneaLink Pro records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse and respiratory effort during sleep. The device uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing or for further clinical investigation. The device is intended for home and hospital use under the direction of a HCP.	Substantially Equivalent Intended use is identical except for last sentence: clarification of use environment only
Intended Environment	Recording - in the home, hospital or other clinical setting Analyzing – physician's practice, sleep laboratory		Equivalent
Target Population	Adults		Equivalent
Channels	- respiratory nasal flow. - oxygen saturation and pulse rate. - respiratory effort	- respiratory nasal flow. - oxygen saturation and pulse rate. - respiratory effort	Equivalent

	PREDICATE	NEW DEVICE	COMMENTS
CHARACTERISTIC	**ApneaLink Plus** (K083575)	**ApneaLink Pro**	**ApneaLink Plus vs. ApneaLink Pro**
Method of connection to the Patient	- Nasal cannula - Optical oximetry finger sensor - Elastic cloth effort belt	- Nasal cannula - Optical oximetry finger sensor - Elastic cloth effort belt	Equivalent
Display operation	Signal LED: 1 LED on the front panel indicates the correct function of patient signals with a green light, and incorrect function by a red light.	Signal LED: 3 LED's beside flow, effort and oximeter connectors indicate correct function of patient signals with a green light, and incorrect function by a red light. *Test complete* light: A *Test complete* LED is provided to signal sufficient recording time.	Substantially Equivalent: ApneaLink Pro: Additional signal LED's introduced to inform user which signal is incorrect. ApneaLink Pro: *Test complete* LED informs user after recording if recording needs to be repeated because of insufficient data
Power Source recorder	Internally powered 2 x batteries: LR6 / Mignon / AA / 1.5V / at least 1.9 Ah or 2 x NiMh accumulators: Mignon / AA / 1.2V / at least 1.9 Ah	Internally powered 2 x batteries: LR03 / Micro / AAA / 1.5V / at least 1.0 Ah or 2 x NiMh accumulators: HR03 / Micro / AAA / 1.2 V / at least 1.0 Ah	Equivalent
Communication Interface	USB 1.1 connector plugged into the device	USB 2.0 connector plugged into the device	Equivalent

	PREDICATE	NEW DEVICE	COMMENTS
CHARACTERISTIC	**ApneaLink Plus** (K083575)	**ApneaLink Pro**	**ApneaLink Plus vs. ApneaLink Pro**
Patient isolation	Device has no galvanic connections to mains as it is a battery-operated device. Not possible to connect auxiliary devices to the device	Device has no galvanic connections to mains as it is a battery-operated device. Not possible to connect auxiliary devices to the device	Equivalent
Sensor Technology	Analog pressure transducer and AD converter	Digital pressure transducer with on-chip calibration	Equivalent
Processor	The processor processes the recorder patient's data	The micro processor system processes the recorder patient's data	Substantially equivalent: Operating principle of collecting and storing data is unchanged
Interface between embedded software and PC software	Recorded data is stored in proprietary data format file.	Recorded data is stored in European Data Format (EDF+) file on SD card. When device is connected to PC via USB the device provides access to its internal memory as mass storage memory including the recorded EDF+ files.	Substantially equivalent: Data is stored in files. Additionally recorder serves as mass storage device.
Analyzing the recorded data	The recorded data are downloaded via USB cable. Data are analyzed and a report can be generated automatically	The recorded data are downloaded via USB cable. Data are analyzed and a report can be generated automatically	Equivalent

	PREDICATE	NEW DEVICE	COMMENTS
CHARACTERISTIC	**ApneaLink Plus** (K083575)	**ApneaLink Pro**	**ApneaLink Plus vs. ApneaLink Pro**
Analysis result (Indices)	The following indices are generated from the ApneaLink Software: AHI, RI, Apnea Index (unclassified, central, mixed, obstructive), Hypopnea Index, Number of flow limited breaths without snoring, Number of flow limited breaths with snoring, Cheyne-Stokes Breathing, ODI, Average saturation, Minimum saturation, Maximum saturation, Basal saturation, Minimum Pulse Rate, Maximum Pulse Rate, Average Pulse Rate	The following indices are generated from the ApneaLink Software: AHI, RI, Apnea Index (unclassified, central, mixed, obstructive), Hypopnea Index, Number of flow limited breaths without snoring, Number of flow limited breaths with snoring, Cheyne-Stokes Breathing, ODI, Average saturation, Minimum saturation, Maximum saturation, Basal saturation, Minimum Pulse Rate, Maximum Pulse Rate, Average Pulse Rate	Equivalent
Dimensions Recorder LxWxD (inches)	4.6" x 2.4" x 1.2"	2.4" x 4" x 1.2"	Substantially Equivalent: Orientation was changed from vertical to horizontal
Dimensions Pulse Oximeter HxWxD (inches)	2.1" x 0.8" x 0.6"	2.1" x 0.8" x 0.6"	Equivalent

The table above shows that there are no significant differences between ApneaLink Pro and the predicate device that adversely affect product safety and effectiveness.

Testing summary

Design and Verification activities have been performed on the ApneaLink Pro as a result of the risk analysis and product requirements. External tests have been conducted for electrical safety, EMC, mechanical and environmental requirements. Additionally, side-by-side testing of the detection of respiratory events and reported indices was used to demonstrate that the ApneaLink Pro is Substantially Equivalent to the ApneaLink Plus (K083575). In the side-by-side testing, the detection of all respiratory events is compared. These include tests comparing pulse/saturation, apnea/hypopnea according classic definition, snoring, Cheyne-Stokes breathing, hypopnea, apnea classification and central apnea determination according to threshold apnea/effort pause. The recorded, analyzed, displayed values and reported apnea classification of obstructive/mixed/central apneas of ApneaLink Pro are compared to those of the ApneaLink Plus. All internal and external tests confirmed that the product meets the predetermined acceptance criteria and the requirements of the relevant standards. No additional biocompatibility testing was required as none of the components in contact with patients have changed from the predicate. ResMed has determined that the ApneaLink Pro is Substantially Equivalent to the predicate device.

Conformance to standards

The ApneaLink Pro complies with the applicable standards and requirements referenced in the following:

- Reviewer Guidance for Premarket Notification Submissions, Anesthesiology and Respiratory Devices Branch (November 1993)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices.(September 9,1999)
- FDA General Principles of Software Validation, Final Guidance for Industry and FDA Staff (January 11, 2002)
- Guidance for Industry and FDA Premarket and Design Control Reviewers Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, 2000
- FDA Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design, 2011
- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: usability
- IEC 60601-1-11 safety Medical electrical equipment – Part 1-11: General requirements for basic and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62304 Medical device software – Software life cycle processes
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 14971 Medical Devices – Application of risk management to medical devices

Conclusion: Based on the results of the performance testing for the ApneaLink Pro and the substantial equivalence comparison to the predicate device no new concerns about safety and effectiveness were raised and we believe that the presented information is sufficient to determine that ApneaLink Pro is substantially equivalent to the predicate device ApneaLink Plus (K083575).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 8, 2013

ResMed Corporation
Mr. Jim Cassi
Vice President – Quality Assurance Americas
9001 Spectrum Center Boulevard
SAN DIEGO, CA 92123

Re: K131932
Trade/Device Name: ApneaLink Pro
Regulation Number: 21 CFR 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: Class II
Product Code: MNR
Dated: October 4, 2013
Received: October 9, 2013

Dear Mr. Cassi:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications For Use Statement

Indication for Use

510(k) Number (if known): K131932

Device Name: ApneaLink Pro

Indication for Use

The ApneaLink™ Pro device is indicated for use by Health Care Professionals (HCP), where it may aid in the diagnosis of sleep disordered breathing for adult patients. ApneaLink Pro records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse and respiratory effort during sleep. The device uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing or for further clinical investigation. The device is intended for home and hospital use under the direction of a HCP.

Prescription Use .....X..... AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.11.07 13:55:09 -05'00'