DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 30, 2015

ResMed Germany Inc.
Ms. Sandra Grunwald
Director Quality Management & Regulatory Affairs
Fraunhoferstr.16
Martinsried, Bavaria 82152
GERMANY

Re: K143272
Trade/Device Name: ApneaLink Air
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: March 25, 2015
Received: March 30, 2015

Dear Ms. Grunwald:

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,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
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Erin I. Keith, M.S.
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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
ApneaLink Air

K143272

Indications for Use *(Describe)*

The ApneaLink™ Air 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 Air records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort and body position 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.

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)

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5 510(k) Summary – ApneaLink Air

510(k) Summary – ApneaLink Air

Date Prepared	30th April 2015
Submitter	Tobias Nagel Manager Regulatory Affairs
Official Contact	Larissa D'Andrea Manager Regulatory Affairs ResMed Corp. 9001 Spectrum Center Boulevard, San Diego, CA 92123 USA Tel: (858) 8366837
Classification Reference	21 CFR 868.2375
Product Code	MNR
Common Name	Ventilatory Effort Recorder
Class Name	Breathing Frequency Monitor
Proprietary Name	ApneaLink Air
Predicate Devices	ApneaLink Pro (K131932) – primary predicate device Nox T3, Noxturnal PC application (K082113)
Reason for submission	Expanded indications

Device Description

ApneaLink Air is a further development of the previously cleared ApneaLink Pro (K131932). ApneaLink Pro was already prepared to support actigraphy but the feature was not activated while ApneaLink Air now offers body position data. The report generated by the ApneaLink (PC) Software remains unchanged from the predicate device, it does neither display data relating body position nor does the body position data influence the calculations made as a result of testing using the ApneaLink Air device, including most importantly, the overall apnea hypopnea index (AHI). The body position data is stored on in the recorder as an EDF+ file and can be displayed using an EDF viewer.

The ApneaLink Air recorder is a 5-channel battery-powered respiratory pressure sensor and oximetry system. ApneaLink Air provides recordings of respiratory pressure, respiratory effort, pulse rate, oxygen saturation and body position during sleep. The physician prescribed device will help to recognize sleep-related respiratory disorders. The ApneaLink Air recorder and the respiratory effort sensor must be fastened with the re-usable belt on the patient's chest parallel to the spine. 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 Air 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 Air recorder. The respiratory effort sensor is connected to the ApneaLink Air 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 Air recorder must be returned to the physician. With the ApneaLink Software the physician can generate a report with the recorded and analyzed data (respiratory pressure, respiratory effort, pulse rate, oxygen saturation) to aid in diagnosis. The body position data is stored as an EDF+ file on the recorder. It is accessible on a computer via USB connection using an EDF viewer.

The recordings and the report can be sent via email to further clinical investigation.

Intended Use

The ApneaLink™ Air 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 Air records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort and body position 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 Air is different from the predicate device ApneaLink Pro (K131932) with respect to:

- Body position recording
  - Actigraphy sensor provides body position of patient during sleep. Data can be viewed via an EDF viewer. Data is neither part of the report generated by ApneaLink Software nor does it influence or alter any index of the report.
- Pulse oximeter module
  - Low power Xpod replaces previous Xpod model. Same accuracy and performance as the existing Xpod, but considerably lower power draw.

Substantial Equivalence

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

ApneaLink Pro (K131932) is the predecessor model of ApneaLink Air and the principal predicate device. With respect to the active body position channel Nox T3 including Noxturnal PC application (K082113) was selected as predicate device.

	Predicates		New Device	Comments
Characteristic	**Nox T3, Noxturnal (PC Application)** (K082113)	**ApneaLink Pro** (K131932)	**ApneaLink Air**	**Predicates vs. ApneaLink Air**
Intended Use	The Nox T3 device is intended for ambulatory recording of physiological signals during sleep. The recorded signals are then downloaded to a PC where the signals can be viewed an analyzed by use of the Nox T3 application (Noxturnal). The Nox T3 system is indicated for use in patients greater than 2 years of age. The Nox T3 system is NOT intended for any patient monitoring or automatic diagnosis. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home. The Nox T3 system is used for patients suspected of suffering from Sleep Disordered Breathing (SDB) or Periodic Limb Movement Disorder	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.	The ApneaLink™ Air 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 Air records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort and body position 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 ApneaLink Air is a further development of the previously cleared ApneaLink Pro (K131932). The modification of the intended use only addresses the additional recording of the body position of the patient during sleep. Body position recording offers additional information to the physician. It does not alter or influence any of the indices (like e. g. AHI or Apnea Index) or data generated by the ApneaLink Software report. Nox T3 incl. Noxturnal PC Application, K082113, has been selected as predicate device for the active body position channel. ApneaLink Air as well as Nox T3 record physiological data during sleep in the same intended environment. This data can be viewed and analyzed using PC software and aid the physician in the diagnosis of sleep disordered breathing.

	PREDICATES		NEW DEVICE	COMMENTS
CHARACTERISTIC	**Nox T3, Noxturnal (PC Application)** (K082113)	**ApneaLink Pro** (K131932)	**ApneaLink Air**	**Predicates vs. ApneaLink Air**
	(PLMD).			Verification and bench testing show that the ApneaLink Air is as safe and effective as the predicate devices and does not raise different questions of safety and effectiveness than the predicate devices. Clinical data with regard to body position recording are not required as the body position data do not alter or influence any of the indices or data generated by the testing and bench testing is sufficient to prove that body position recording results are as accurate as specified.
Intended Environment	The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home	Recording - in the home, hospital or other clinical setting Analyzing – physician's practice, sleep laboratory		Equivalent
Target Population	Patients greater than 2 years	Adults		Substantially Equivalent Equivalent with ApneaLink Pro. Equivalent with Nox T3 regarding adult patients

	PREDICATES		NEW DEVICE	COMMENTS
CHARACTERISTIC	**Nox T3, Noxturnal (PC Application)** (K082113)	**ApneaLink Pro** (K131932)	**ApneaLink Air**	**Predicates vs. ApneaLink Air**
Channels	- air flow - nasal/mask pressure - oxygen saturation - pulse - respiratory effort (abdomen and thorax) - **body position** - activity - snore - respiratory sound - EEG, EOG, EMG, ECG	- flow channel for measurement of patient respiratory nasal pressure. - oximeter input to measure degree of oxygen saturation of the blood and pulse rate. - effort channel to measure the respiratory effort using a pneumatic principle.	- flow channel for measurement of patient respiratory nasal pressure. - oximeter input to measure degree of oxygen saturation of the blood and pulse rate. - effort channel to measure the respiratory effort using a pneumatic principle. - **body position** channel to determine body position of the patient during sleep	Substantially Equivalent The body position channel was already implemented in the predicate device ApneaLink Pro but not activated. In the ApneaLink Air the additional channel is activated. Body position recording offers additional information to the physician. It does not alter or influence any of the indices (like e. g. AHI) or Apnea Index or data generated by the ApneaLink Software report. The ApneaLink Air device shows similar to the Nox T3 body position information according to the angle the device is tilted or rotated. Additional channels of Nox T3 not relevant for body position.
Method of connection to the Patient	Plastic tubing and cannula for pressure sensing; RIP belts for respiratory effort; probes or Flexi Wrap for oximetry; touch proof electrode cables; RIP belts for attaching of device and clip straps to secure position of device.	Plastic tubing and cannula for pressure sensing; elastic cloth material belt to support unit and the respiratory effort sensor. The device is to be attached to a patient's chest. The Xpod is fixed at the belt via clip. Flexi Wrap to fix the oximeter sensor to the	Plastic tubing and cannula for pressure sensing; elastic cloth material belt to support unit and the respiratory effort sensor. The device is to be attached to a patient's chest. The new low power Xpod is fixed at the belt via clip. Flexi Wrap to fix the oximeter	Equivalent

	PREDICATES		NEW DEVICE	COMMENTS
CHARACTERISTIC	**Nox T3, Noxturnal (PC Application)** (K082113)	**ApneaLink Pro** (K131932)	**ApneaLink Air**	**Predicates vs. ApneaLink Air**
	The device is worn on the patient's chest.	patient's finger.	sensor to the patient's finger.	
Display operation	The device has a display to view signal integrity and operation of the device.	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
Power Source recorder	Internally powered 1x battery LR6 / Mignon / AA/ 1.5V or 1x NiMh AA/1.5V	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		Substantially equivalent
Communication Interface	USB 2.0	USB 2.0 connector plugged into the device		Equivalent
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			Equivalent
Sensor Technology	Solid state pressure sensor Solid state position/activity sensor Respiratory Effort Sensors (RIP technology) Oximetry	Utilizes solid-state pressure sensor for nasal flow and effort that converts pressure changes to electrical signal levels Utilizes oximetry sensor	Utilizes solid-state pressure sensor for nasal flow and effort that converts pressure changes to electrical signal levels Utilizes oximetry sensor Utilizes solid-state actigraphy	Substantially Equivalent

	PREDICATES		NEW DEVICE	COMMENTS
CHARACTERISTIC	**Nox T3, Noxturnal (PC Application)** (K082113)	**ApneaLink Pro** (K131932)	**ApneaLink Air**	**Predicates vs. ApneaLink Air**
			sensor for position	
Processor	Microprocessor system processes the recorder patient's data	The microprocessor system (LPC1853/7) processes the recorder patient's data	The microprocessor system (LPC1853) processes the recorder patient's data	Substantially Equivalent Sole difference between the microprocessor systems of ApneaLink Pro (K131932) and ApneaLink Air is the internal flash memory size (500kB in LPC1857 vs. 1MB in LPC1853)
Location of linearization (Transformation of pressure values in flow values)	No transformation. Airflow is displayed as pressure value.	ApneaLink Pro recorder	ApneaLink Air recorder	Substantially Equivalent Difference between Nox T3 (K082113) and ApneaLink Air is not relevant for body position recording.
Interface between embedded software and PC software/EDF viewer	Recorded data is stored in the device. When the device is connected to PC via USB cable the device provides access to its internal memory All recorded data will be transferred to the Noxturnal PC	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. Data related to patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse,	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. Data related to patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse,	Substantially Equivalent In addition to the transfer of the data recorded by the predicate device ApneaLink Pro (K131932) ApneaLink Air offers the possibility to access body position data by an EDF viewer. No differences between Nox T3

	Predicates		New Device	Comments
Characteristic	**Nox T3, Noxturnal (PC Application)** (K082113)	**ApneaLink Pro** (K131932)	**ApneaLink Air**	**Predicates vs. ApneaLink Air**
	application software.	respiratory effort can be transferred to the ApneaLink Software.	respiratory effort can be transferred to the ApneaLink Software. Body position data can be accessed by an EDF viewer.	(K082113) and ApneaLink Air that are relevant for body position recording/displaying.
Analyzing the recorded data	The recorded data are downloaded via USB cable. Data related to air flow, nasal/mask pressure, snoring, oxygen saturation, pulse, respiratory effort (abdomen and thorax), body position, activity, respiratory sound, EEG, EOG, EMG and ECG can be analyzed by the Noxturnal Software and a report can be generated automatically.	The recorded data are downloaded via USB cable. Data can be accessed via EDF viewer. Data related to patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort can be analyzed by the ApneaLink Software and a report can be generated automatically.	The recorded data are downloaded via USB cable. Data can be accessed via EDF viewer. Data related to patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort can be analyzed by the ApneaLink Software and a report can be generated automatically. Body position data can be viewed using an EDF viewer.	Substantially Equivalent Additional channels of Nox T3 not relevant for body position.
Analysis result (Indices)	The following indices are generated from the Noxturnal Software: AHI, Apnea Index, Apneas (central, mixed, obstructive), Hypopnea Index, Hypopneas, Snore Index, Flow Limitation Index, Longest Apnea/Hypopnea, Average Apnea, Average Hyponea, Desaturation Index/Count, SpO_2 (Lowest, average,	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		Substantially equivalent Recorded body position data can be viewed using an EDF viewer but is not displayed in the report generated by the ApneaLink Software. The body position data does not alter or influence any of the mentioned indices like e. g. AHI or Apnea Index. Information regarding body position serves as additional information. Thus the

	PREDICATES		NEW DEVICE	COMMENTS
CHARACTERISTIC	**Nox T3, Noxturnal (PC Application)** (K082113)	**ApneaLink Pro** (K131932)	**ApneaLink Air**	**Predicates vs. ApneaLink Air**
	baseline), Desaturation <90%, <85%, SpO_2 time <90%, <85%, Pulse (Average, Highest, Lowest), Pulse time <40bpm, >100bpm, Average (Pulse SD, Desat Drop, Low Desat), Supine/non-supine time, upright time, activity time, Invalid data time, oximeter quality, flow quality, RIP quality, paradoxical index, est. sleep efficiency, respiration rate			indices generated from the ApneaLink Software in the report remain unchanged. Additional analysis results of Nox T3 not relevant for body position.
ISO 10993-1 (Biocompatibility testing)	Cleared under K082113	Cleared under K131932	Identical materials are used from ApneaLink Pro (K131932) with the same type and duration of patient contact.	Equivalent
IEC 60601-1-2 (EMC)	Cleared under K082113	Cleared under K131932	Radiated emission for the combination of ApneaLink Air with the new low power Xpod has been retested to verify the combination has equivalent emission behavior compared to the previous device and is still significantly below the limits.	Equivalent
IEC 60601-1 (Electrical	Cleared under K082113	Cleared under K131932	ApneaLink Pro (K131932) was tested for IEC 60601-1. Test	Equivalent

	Predicates		New Device	Comments
Characteristic	**Nox T3, Noxturnal (PC Application)** (K082113)	**ApneaLink Pro** (K131932)	**ApneaLink Air**	**Predicates vs. ApneaLink Air**
safety)			results remain valid for ApneaLink Air. The actigraphy sensor was already physically incorporated in ApneaLink Pro. The new low power Xpod was successfully tested for compliance with IEC 60601-1 by manufacturer Nonin. The combination of both devices introduces no additional electrical safety risk as the low power Xpod is powered by ApneaLink Air and has no additional power source.	
Environmental testing	Cleared under K082113	Cleared under K131932	ApneaLink Pro (K131932) was tested for IEC 60601-1-11. Test results remain valid for ApneaLink Air.	Equivalent
Dimensions Recorder LxWxD (inches)	2.48“ x 3.11“ x 0.83“	2.4“ x 4“ x 1.2“		Equivalent
Xpod oximeter	Nonin 3150 Pulse oximeter Nonin 4100 Pulse oximeter	Nonin Xpod 3012	Nonin Xpod 3012 LP .	Substantially Equivalent ApneaLink Pro was tested for IEC 60601-1 (K131932). Test results remain valid for ApneaLink Air. The new low power Xpod was successfully tested for compliance with IEC 60601-1 by manufacturer

	Predicates		New Device	Comments
Characteristic	**Nox T3, Noxturnal (PC Application)** (K082113)	**ApneaLink Pro** (K131932)	**ApneaLink Air**	**Predicates vs. ApneaLink Air**
				Nonin. The combination of both devices introduces no additional electrical safety risk as the low power Xpod is powered by ApneaLink Air and has no additional power source. Xpod 3012 and Xpod 3012 LP have equivalent performance and clinical accuracy. Different types of pulse oximeters used with Nox T3 and ApneaLink Air are not relevant for body position recording.
Dimensions Pulse Oximeter HxWxD (inches)	N/A	2.1“ x 0.8“ x 0.6“		Equivalent

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

Testing summary

Design and system verification testing in regards to mechanical and environmental testing according to IEC 60601-1-11:2010, electrical safety testing according to IEC 60601-1:2005 and EMC testing according to IEC 60601-1-2:2007 has been performed. All features that were changed from the predicate device ApneaLink Pro (K131932) are covered by additional verification testing as required. Detection of respiratory events and reported indices was cleared under K083575 (ApneaLink Plus) and remained unchanged in ApneaLink Pro (K131932) and ApneaLink Air. Thus side-by-side testing results from ApneaLink Pro comparing detection of all respiratory events remain valid.

Mechanical verification testing was performed on the subject device. The mechanical testing includes the following:

- Specification Conformance Testing
- Cleaning and Disinfection Test
- Durability Testing for the connectors, the button, the battery cap and battery contact
- Screw Stripping
- Sharp Edges Test
- Pressure Test

The device and the tested components passed the mechanical verification tests. Additional side by side testing has been performed by using a protractor to show the defined position around the body axis for ApneaLink Air and Nox T3.

All tests confirmed that the subject device meets the predetermined acceptance criteria and the requirements of the relevant standards. ResMed has determined that the ApneaLink Air is Substantially Equivalent to the predicate devices.

Conclusion: Based on the results of the performance testing for ApneaLink Air and the substantial equivalence comparison with the predicate devices with regard to the active body position channel no new concerns about safety and effectiveness were raised and we believe that the presented information is sufficient to determine that ApneaLink Air is substantially equivalent to the predicate devices ApneaLink Pro, K131932, and Nox T3, Noxturnal (PC Application), K082113.