K082575

510(k) Summary – ApneaLink Plus

MAR 1 9 2009

Date Prepared	28th November 2008
Official Contact	David D'Cruz V.P., Clinical & Regulatory Affairs ResMed Corp. 14040 Danielson St, Poway CA 92064-6857 USA Tel: +1 858-746-2238 Fax: +1 858-746-2915
Classification Reference	21 CFR 868.2375
Product Code	MNR – Ventilatory Effort Recorder
Common/Usual Name	Ventilatory Effort Recorder
Proprietary Name	ApneaLink Plus
Predicate Devices	ApneaLink (K070263) Respironics Stardust II (K021845)
Reason for submission	Expanded Indications

Substantial Equivalence

The new device has the following similarities to the previously cleared devices:

- Intended use Similar
- Operating principle Same
- Technologies Same
- Manufacturing process Same

Design and Verification activities were performed on the ApneaLink Plus as a result of the risk analysis and product requirements. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the ApneaLink Plus is Substantially Equivalent to the predicate devices. The ApneaLink complies with the applicable standards and requirements referenced in the following:

- FDA Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Off-the-Shelf Software Use in Medical Devices (September 9,1999)
- FDA General Principles of Software Validation (January 11, 2002)
- 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 safety – Collateral standard: Electromagnetic compatibility – Requirements and tests)
- IEC 60601-1-4 (Medical Electrical Equipment Part 1-4: General requirements for safety Collateral Standard: Programmable electrical medical systems)
- IEC 60068-2-1/ and the following (Environmental testing)
- ISO 10993-1 (Biological evaluation of medical devices – Part 1 Evaluation and testing)
- EN ISO 14971 (Medical Devices – Application of risk management to medical devices)

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.

Device Description

The performance and functional characteristics of ApneaLink Plus includes all the user-friendly features of the predicate devices. The ApneaLink Plus is a further development of the previously submitted device ApneaLink (K070263). This submission addresses the expanded Indications for Use of ApneaLink by including AASM criteria for detecting hypopneas and a respiratory effort sensor to differentiate between central, obstructive and mixed apneas.

The ApneaLink Plus recorder is a 3-channel battery-powered respiratory pressure sensor and oximetry system. ApneaLink Plus 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 and lead to comprehensive clinical diagnosis and therapy. The patient may perform the recording at home by himself. The ApneaLink Plus 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 Plus 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 Plus recorder. The respiratory effort sensor is connected to the ApneaLink Plus recorder and held in place by the belt. After recording, the ApneaLink Plus recorder must be returned to the physician. With the ApneaLink Plus Software installed on a personnel computer the physician can generate a report with the recorded and analyzed data to aid in the diagnosis of sleep disordered breathing. The recordings and the report can be sent via email to further clinical investigation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2009

ResMed Germany, Incorporated
C/O Mr. David D'Cruz
Vice President, Clinical & Regulatory Affairs
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K083575
Trade/Device Name: ApneaLink Plus
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: March 3, 2009
Received: March 5, 2009

Dear Mr. D'Cruz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: ApneaLink Plus

Indication for 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.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083575