TAB 5

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

JUN 26 2009

Official Contact

Zita A. Yurko
Director, Regulatory Affairs
Respironics, Inc.
1001 Murry Ridge Lane
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Classification Reference	21 CFR 868.2375
Product Code	MNR – Ventilatory Effort Recorder
Common/Usual Name	Ventilatory Effort Recorder
Proprietary Name	Alice PDx
Predicate Device(s)	Respironics Galaxy (K083874)
Reason for submission	Modified device

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device:

- Same intended use.
- Same operating principle.
- Same technology.
- Same manufacturing process.

Design verification tests were performed on the Alice PDx as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate device.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices," May 2005.

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. 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.

Device Description

The Alice PDx is a wearable data recorder that collects and stores physiological signals. The role of the Alice PDx is only to record the data. The following physiological signals may be collected and stored by the Alice PDx device:

- EEG, EOG, EMG, ECG
- Nasal/oral Airflow
- Snore
- Thoracic and Abdominal Effort
- Body Position
- Pulse Oximetry, including:
  - Oxygen Saturation (SpO_2)
  - Pulse Rate
  - Plethysmograph

The recorded data is stored on a secure digital (SD) card and may be passed on to a PC for analysis and reporting of the data by the Respironics Sleepware Software application. The Alice PDx data recorder is not in any way involved in the data management performed by the host.

(End of Tab.)

ATT 2:

510(k) Summary of Safety & Effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2009

Mr. Zita A. Yurko
Director, Regulatory Affairs
Respironics, Incorporated
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K090484
Trade/Device Name: Respironics Alice PDx
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: May18, 2009
Received: May19, 2009

Dear Mr. Yurko:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090484

Device Name: Respironics Alice PDx

Intended Use/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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

L Schutter

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

510(k) Number: K090484