TAB 3

K072048

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact

Zita A. Yurko
Director, Regulatory Affairs
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668
Zita.yurko@respironics.com

724-387-4120 t
724-882-4120 c
724-387-4216 f

MAY - 8

Classification Reference	21 CFR 868.5905
Product Code	BZD - – ventilator, non-continuous (respirator)
Common/Usual Name	CPAP System
Proprietary Name	Respironics REMstar M-Series Auto with AFLEX CPAP System
Predicate Device(s)	Respironics REMstar AFLEX CPAP System (K063830)
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 Respironics REMstar M-Series Auto with AFLEX System 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 devices.

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 2006.

Intended Use

The Respironics REMstar M-Series Auto with AFLEX CPAP System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30kg. For use in the home or hospital/institutional environment.

Device Description

The Respironics REMstar M-Series Auto with AFLEX CPAP System is a microprocessor controlled blower based positive pressure system with integrated heated humidifier. The REMstar M-Series Auto with AFLEX System also includes the auto mode and the flex therapy feature cleared in K063830 which provides the patient with additional comfort by easing the transition from the end of inspiration to the beginning of exhalation. In addition the device includes an AFLEX therapy feature which provides added comfort for the user. As stated in the submission, the purpose of this modification is to provide enhanced event detection and algorithm response to these new event types. Like its predicate, this device is intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen 22mm tubing, an exhalation device, and a patient interface device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2009

Ms. Zita A. Yurko
Director, Regulatory Affairs
Respironics Incorporated, Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K090243
Trade/Device Name: Respironics REMstar M-Series Auto with AFLEX CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 9, 2009
Received: April 10, 2009

Dear Ms. 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

Enclosure

510(k) Number (if known): _____

Device Name: Respironics REMstar M-Series Auto with AFLEX CPAP System

Intended Use/Indications for Use

The Respironics REMstar M-Series Auto with AFLEX CPAP System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30kg.

Environment of Use/Patient Population

For use in the home or hospital/institutional environment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription UseXXXXX_____ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number: K090243