DEC 16 2011

Tab 4

510(K) Summary of Safety & Effectiveness

Official Contact	Frank Kadi Senior Regulatory Affairs Engineer Respironics, Inc. 1740 Golden Mile Highway Monroeville, PA 15146
Date Prepared	23 November 2011
Trade Name	REMstar Auto A-Flex HT
Common Name	CPAP System
Classification Name	ventilator, non-continuous (respirator) (21 CFR 868.5905, Product Code BZD)
Predicate Device(s)	REMstar Auto A-Flex (K091319)
Reason for Submission	The REMstar Auto A-Flex HT is the result of modifications made to the REMstar Auto A-Flex (K091319) for the purpose of introducing optional heated tubing. Implementation of heated tubing required modifications to the software, electrical and mechanical design of the device including the addition of a resistive-wire heating element.

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 REMstar Auto A-Flex HT 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 requirements of the following FDA Guidance Documents:

- FDA Reviewers Guidance for Premarket Notification Submissions (November 1993)
- FDA Reviewers Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

Intended Use

The REMstar Auto A-Flex HT delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30kg (66 lbs). It is for use in the home or hospital/institutional environment.

Device Description

The REMstar Auto A-Flex HT is a microprocessor controlled blower based positive pressure system which is comprised of the therapy device, a heated humidifier and patient tubing (15mm, 22mm, or heated tubing).

The REMstar Auto A-Flex HT includes CPAP and Auto CPAP therapy modes. While in CPAP mode, the device delivers a continuous positive airway pressure throughout the entire therapy session. While in Auto CPAP mode, the device delivers a positive airway pressure that automatically adjusts to the patient's needs as various breathing events, such as apneas and hypopneas, are detected.

In addition to CPAP and Auto CPAP therapy modes, the REMstar Auto A-Flex HT incorporates several optional features to aid with patient comfort. These features include ramp, adjustable pressure relief (FLEX technologies), and humidification. Humidification options include both a heated humidifier and heated tubing. The heated humidifier adjusts the level of humidification by varying the temperature of a heated plate used to heat up a chamber of water. Optional heated tubing can then be used to maintain that air at a desired temperature until it reaches the patient's mask. This is accomplished through a resistive-wire heating element embedded in the tubing wall.

The REMstar Auto A-Flex HT is intended for use with a patient circuit that connects the device to a patient interface device (mask). A typical patient circuit consists of patient tubing (15mm, 22mm, or heated tubing) and an exhalation device (if one is not present in the mask). When a heated humidifier is attached to the therapy device, the patient circuit connects to the air outlet port of the heated humidifier.

Non-Clinical Tests

Verification activities performed to verify that the device modifications did not affect the safety and effectiveness of the subject device included the following:

Heated Tubing Performance

Heated Humidifier performance has been verified to meet product specifications through all Humidity Level settings.

Heated Tubing Controls and Indicators

The controls and indicators related to the Heated Tubing modification have been verified to be working as intended.

Heated Tubing Maximum Outlet Air Temperature

The maximum air temperature delivered to the patient has been verified to not exceed 41°C.

Heated Tubing Error Handling

The REMstar Auto A-Flex HT has been verified to detect and respond to error conditions related to the heated tubing functionality.

Heated Tubing Materials

Heated tubing materials used in the air flow path of the device have been verified to meet the requirements of ISO 10993-1 (Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process).

Safety Evaluation

The REMstar Auto A-Flex HT has been designed to meet the requirements of IEC 60601-1 (Medical Electrical Equipment – General requirements for safety)

Electromagnetic Compatibility

The REMstar Auto A-Flex HT has been designed to meet the electromagnetic compatibility requirements as defined by the FDA Reviewer Guidance for Premarket Notification Submissions (Nov 1993).

Mechanical Stress Testing

The REMstar Auto A-Flex HT has been designed to meet mechanical stress requirements as defined by the FDA Reviewer Guidance for Premarket Notification Submissions (Nov 1993).

Transportation Testing

Transportation tests were performed using the REMstar Auto A-Flex HT in all final packaging configurations. Functional tests were used to verify device performance post shipping.

Clinical Tests

Clinical tests were not required to demonstrate the safety and effectiveness of the REMstar Auto A-Flex HT. Product functionality has been adequately assessed by non-clinical tests.

Conclusion

The REMstar Auto A-Flex HT has passed all of the aforementioned non-clinical tests and required no clinical tests in order to demonstrate safety or effectiveness. It is therefore concluded that the REMstar Auto A-Flex HT is substantially equivalent to the predicate device in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Respironics, Incorporated
C/O Mr. Frank Kadi
Senior Regulatory Affairs Engineer
Sleep & Home Respiratory Care
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

DEC 16 2011

Re: K113068
Trade/Device Name: REMstar Auto A-Flex HT
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: November 23, 2011
Received: November 25, 2011

Dear Mr. Kadi:

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.

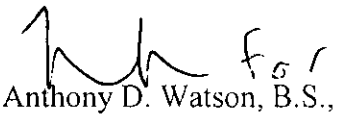
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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/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,



Anthony D. Watson, B.S., M.S., M.B.A.
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): K113068

Device Name: REMstar Auto A-Flex HT

Indications for Use:

The REMstar Auto A-Flex HT delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30kg (66 lbs). It is for use in the home or hospital/institutional environment.

Prescription Use ___✓___		**Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D)	**AND/OR**	**(Part 21 CFR 801 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: K113068