Tab 5

510(K) Summary of Safety & Effectiveness K122769

OCT 9 2012

Official Contact	Frank Kadi Senior Regulatory Affairs Engineer Respironics, Inc. 1740 Golden Mile Highway Monroeville, PA 15146
Date Prepared	30 January 2012
Trade Name	REMstar SE
Common Name	CPAP System
Classification Name	ventilator, non-continuous (respirator) (21 CFR 868.5905, Product Code BZD)
Predicate Device(s)	Respironics REMstar Auto A-Flex HT (K113068) Respironics SleepEasy CPAP System (K091112) Respironics REMstar Plus CPAP System (K010263)
Reason for Submission	The REMstar SE is the result of modifications made to the REMstar Auto A-Flex HT (K113068). The goal of these modifications is to combine the updated platform design of the REMstar Auto A-Flex HT (K113068) with both the feature set and performance aspects of the SleepEasy CPAP System (K091112) and the REMstar Plus CPAP System (K010263). In addition, modifications have been made in regards to flow detection, and humidity control. The necessary modifications have been accomplished via a combination of software, electrical and mechanical design changes.

Substantial Equivalence

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

- Same Intended Use
- Same operating principle
- Same technology
- Same manufacturing process

Design verification tests were performed on the REMstar SE 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 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 SE 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 SE 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 SE includes a CPAP mode only. While in CPAP mode, the device delivers a continuous positive airway pressure throughout the entire therapy session.

In addition to the CPAP therapy mode, the REMstar SE 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.

The REMstar SE 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:

Flex Performance

Flex performance has been verified to meet product specifications for each level of control.

Pressure Stability

Pressure stability performance for the REMstar SE has been verified across all environmental conditions including altitude, temperature, and humidity.

Humidifier Performance

Humidifier performance has been verified to meet product specifications for humidity output.

Standards Evaluation

The REMstar SE has been designed to meet the requirements of the following FDA Recognized Consensus Standards:

- ISO 14971 *Medical devices – Application of risk management to medical devices*
- ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- IEC 60601-1 *Medical Electrical Equipment – Part 1: General Requirements of Safety*
- IEC 62304 *Medical device software – Software life cycle processes*
- ISO 5356-1 *Anaesthetic and respiratory equipment – Conical connectors: Part 1L Cones and sockets*

Clinical Tests

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

Conclusion

The REMstar SE 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 SE 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

OCT 9 2012

Respironics, Incorporated
Mr. Frank Kadi
Senior Regulatory Affairs Engineer
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K122769
Trade/Device Name: REMstar SE
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 7, 2012
Received: September 11, 2012

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,

for

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): K122769

Device Name: REMstar SE

Indications for Use:

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

L Schultz

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

510(k) Number: K122769