K130077

MAY 2 1 2013

Tab 5

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	11 January 2013
Trade Name	REMstar SE
Common Name	CPAP System
Classification Name	ventilator, non-continuous (respirator) (21 CFR 868.5905, Product Code BZD)
Predicate Device	Respironics REMstar SE (K122769)
Reason for Submission	The modified device is the result of a material modifications made to the REMstar SE (K122769).

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 material modification has 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 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 modification did not affect the safety and effectiveness of the subject device included the following:

Material Evaluation

New materials used in the air flow path of the device have been verified to be acceptable for use through the following biocompatibility tests, in accordance with ISO 10993-1:

- Implantation (per ISO 10993-6)
- Genotoxicity (per ISO 10993-3)
- Irritation (per ISO 10993-10)
- Cytotoxicity (per ISO 10993-5)
- Sensitization (per ISO 10993-10)

The cleaning and disinfection methods identified in the product labeling were validated in order to demonstrate that the device is safe and effective for single-patient reuse and multi-patient use. Performance testing was completed to demonstrate the ability of the device to withstand the maximum number of recommended cleaning and disinfection cycles, and disinfection efficacy testing was performed to demonstrate the ability of the disinfection methods to disinfect the device. The device met the acceptance criteria for the performance tests after the maximum recommended cycles of cleaning and disinfection, and the disinfection methods were found to be effective.

Volatile Organic Compounds (VOC) testing was performed and demonstrated ability of modified device to meet established guidelines for the output of Volatile Organic Compounds (VOCs), carbon dioxide and carbon monoxide.

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 Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2013

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

Re: K130077
Trade/Device Name: REMstar SE
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: April 24, 2013
Received: April 25, 2013

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 contact 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. 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,

Kwame O. Ulmer for -S FDA

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130077

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

Paul H. Shin -S
2013.05.16 11:48:30 -04'00'

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

510(k) Number: K130077