Tab 4

510(K) Summary of Safety & Effectiveness

Official Contact	Michelle Brinker Senior Manager, Regulatory Affairs Respironics, Inc. 1740 Golden Mile Highway Monroeville, PA 15146 Phone: 724-387-4146
Date Prepared	June 25, 2013
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)	Respironics REMstar Auto A-Flex HT (K113068)
Reason for Submission	The REMstar Auto A-Flex HT is the result of modifications made to the REMstar Auto A-Flex HT (K113068) to include GPAP extended duration ramp and patient-adjustable ramp time, several auto CPAP therapy modalities/features, and humidifier options.

OCT 18 2013

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.

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 delivers CPAP and Auto CPAP therapy. With CPAP therapy, the device provides a continuous positive airway pressure throughout the entire therapy session. With Auto CPAP therapy, the device provides 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 the CPAP and Auto CPAP therapy, 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. Two ramp options are available, ramp and GPAP, in which therapy pressure gradually increases (ramps) to the prescription pressure. The therapy pressure increases to the prescription pressure over minutes with the standard ramp feature and over days with the GPAP extended duration ramp feature. 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 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

Design verification tests were performed for each modification to the REMstar Auto A-Flex HT based on the risk analysis. The testing confirmed that device met the pre-determined acceptance criteria. Results from the performance testing demonstrate that the REMstar Auto A-Flex HT meets its performance specifications, raises no new issues of safety or effectiveness, and is substantially equivalent to the identified predicate device.

The REMstar Auto A-Flex HT 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 for Safety*
- IEC 60601-1-2 *Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests*
- IEC 62304 *Medical device software – Software life cycle processes*
- ISO 5356-1 *Anaesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets*

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

October 18, 2013

Respironics, Incorporated
Ms. Michelle Brinker
Senior Manager, Regulatory Affairs
1740 Golden Mile Highway
Monroeville PA 75146

Re: K131982
Trade/Device Name: REMstar Auto A-Flex HT
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (Intermittent Positive Pressure Breathing–IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 17, 2013
Received: September 18, 2013

Dear Ms. Brinker:

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,

Mary S. Brinner -S

Kwame Ulmer M.S.
Acting Division 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): K131982

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 ___✓___ **(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)

Anya C. Harry -S Digitally signed by Anya C. Harry -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590 Date: 2013.10.18 12:37:03 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices.
510(k) Number K131982