TAB 3

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Date	April 19, 2004
Official Contact	Zita A. Yurko Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Phone: 724-387-4120 Fax: 724-387-4216 Email: Zita.Yurko@Respironics.com
Classification Reference	21 CFR 868.5905
Product Code	BZD – Non-Continuous ventilator
Common/Usual Name	CPAP System
Proprietary Name	Respironics REMstar Auto with C-Flex CPAP System
Predicate Device(s)	Respironics REMstar Auto CPAP System (K012554/K031460) Respironics REMstar Pro with C-Flex CPAP System (K021861)
Reason for submission	Modified design, enhanced mode.

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 Respironics REMstar Auto with C-Flex CPAP 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 device.

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 1998.

Intended Use

The REMstar Auto with C-Flex CPAP System is intended to provide CPAP (Continuous Positive Airway Pressure) for the treatment of adult Obstructive Sleep Apnea (OSA) only. The REMstar Auto with C-Flex may be used in the home or hospital/institutional environment.

Device Description

The Respironics REMstar Auto with C-Flex CPAP System is a microprocessor controlled blower based continuous positive pressure system. Respironics is adding an additional therapy feature to provide pressure relief during exhalation. The REMstar Auto with C-Flex CPAP System provides CPAP or Auto CPAP therapy with or without the C-Flex function and 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, a method of venting exhaled gases, and a patient interface device.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Ms. Zita Yurko
Regulatory Affairs Manager
Respironics, Incorporated
1001 Murry Ridge Lane
Murrysville, PA 15668

Re: K041010
Trade Name: REMstar Auto with C-Flex CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: April 19, 2004
Received: April 20, 2004

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041010

Device Name: REMstar Auto with C-Flex CPAP System

Indications for Use:

The REMstar Auto with C-Flex CPAP System is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only. The device is for use in the home or hospital/institutional environment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K041010