TAB 3

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact	Zita A. Yurko Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 724-387-4120 724-387-4206 (fax) 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 Pro M Series CPAP System
Predicate Device(s)	Respironics REMstar Pro with C-Flex CPAP System (K021861)
Reason for submission	Modified design.

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 Respironics REMstar Pro M Series 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 devices.

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 2005.

Intended Use

The Respironics REMstar Pro M Series CPAP System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30kg. For use in the home or hospital/institutional environment.

Device Description

The Respironics REMstar Pro M Series CPAP System is a smaller and lighter microprocessor controlled blower based positive pressure system with integrated heated humidifier. The REMstar Pro M Series CPAP System also includes the flex therapy feature cleared in K021861 which provides the patient with additional comfort by easing the transition from the end of inspiration to the beginning of exhalation. Like its predicate, the REMstar Pro M Series CPAP System 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, an exhalation device, and a patient interface device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

Ms. Zita A. Yurko
Manager, Regulatory Affairs
Respironics, Incorporated
Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K052110
Trade/Device Name: M-SERIRES PRO CPAP SYSTEM
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 20, 2005
Received: September 21, 2005

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number (if known): _____

Device Name: Respironics REMstar Pro M Series CPAP System

Intended Use/Indications for Use

The Respironics REMstar Pro M Series CPAP System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30kg.

Environment of Use/Patient Population

For use in the home or hospital/institutional environment.

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription UseXXXXX_____ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number: K052110