TAB 5

510(K) SUMMARY

FEB 22 2007

Date of Submission	22 November 2006
Official Contact	Zita A. Yurko Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Zita.yurko@respironics.com 724-387-4120 t 724-882-4120 c 724-387-4216 f
Classification Reference	21 CFR 868.5895
Product Code	MNS – Non-Continuous ventilator
Common/Usual Name	Ventilator, continuous, non-life supporting
Proprietary Name	Respironics BiPAP AutoSV Ventilatory Support System
Predicate Device(s)	Respironics BiPAP Synchrony HC (K992530) Respironics BiPAP Synchrony S/T (K012323) Respironics BiPAP Harmony (K031656) Resmed VPAP III ST-A / Kidsta system (K060105)
Reason for submission	new device

Substantial Equivalence

The BiPAP AutoSV has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.

- ❑ Same manufacturing process.

The BiPAP Synchrony was cleared in K992530/K012323/K020777. The VPAP Adapt was cleared in K051364. Respironics has performed a risk analysis to identify the consideration of using the existing BiPAP Synchrony electromechanical platform with the AutoSV algorithm to treat adult patients with OSA and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing. To determine equivalence between the Respironics BiPAP AutoSV and the Resmed VPAP Adapt, comprehensive bench testing was performed. This testing including collecting waveform performance data, triggering data, alarms data, and overall event diction and control data for comparison to the VPAP Adapt. Bench testing has confirmed that the BiPAP AutoSV performs equivalently to the device predicate VPAP Adapt (K051364). All tests were verified to meet the required acceptance criteria.

Intended Use

The BiPAP AutoSV is intended to provide non-invasive ventilatory support to treat adult patients with OSA and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing.

Device Description

The Respironics BiPAP AutoSV is a microprocessor controlled blower based Bi-level positive pressure system that delivers two positive pressure levels (IPAP/EPAP). The dual pressure levels provide a more natural means of delivering pressure support therapy to the patient resulting in improved patient comfort. A flow sensor and redundant pressure sensors in the patient airway feed data on measured flow and pressure into a microprocessor controller, which in turn regulates the blower assembly. A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters.

The BiPAP AutoSV pressure control that contains various controls which are used to configure positive pressure therapies. With these controls, the device delivers minimum pressure support determined by the EPAP and IPAP Min controls. The device may automatically provide additional pressure support with inspiratory pressures between IPAP Min and IPAP Max to normalize patient ventilation during sleep disordered breathing events. **Note**: When EPAP < IPAP Min = IPAP Max, this is equivalent to traditional bi-level therapy.

The BiPAP AutoSV is fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable.

The BiPAP AutoSV Ventilatory Support 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, a method of venting exhaled gases..

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

FEB 2 2 2007

Re: K063540
Trade/Device Name: BiPAP AutoSV
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: November 22, 2006
Received: November 24, 2006

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,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ___BiPAP AutoSV_____

The BiPAP AutoSV is intended to provide non-invasive ventilatory support to treat adult patients with OSA and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Will Maloy for M. Hosband

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

(Number) K063540