TAB 5

510(K) SUMMARY

K090539

Date of Submission	23 February 2009
Official Contact	Zita A. Yurko Director, 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 Advanced
Predicate Device(s)	Respironics BiPAP AutoSV (K063540) Respironics BiPAP Synchrony 2 (K063533)
Reason for submission	new device

OCT 30 2009

Substantial Equivalence

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

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

The BiPAP AutoSV was cleared in K063540. The BiPAP Synchrony 2 (new platform) was cleared in K063533. To update the device platform for the BiPAP AutoSV algorithm, the device platform cleared in K063533 was used. This platform updates the styling of the device and allows for an interface to an integrated heated humidifier. In addition to this update, some modifications to improve the performance of the device. These included improved event detection, use of EPAP Control for pressure control when central events are detected and improving the response time of the backup rate. Because these modifications affected the AutoSV algorithm, it was determined that these device modifications required clinical validation to ensure the efficacy of the algorithm was not affected. The remainders of the device modifications were validated using bench data. This testing including collecting waveform performance data, triggering data, and overall event detection and control data for comparison to the BiPAP AutoSV device (K063540). This testing has confirmed that the BiPAP AutoSV Advanced performs equivalently to the device predicate BiPAP AutoSV (K063540). All tests were verified to meet the required acceptance criteria.

Intended Use

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

The BiPAP AutoSV Advanced 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 Advanced 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 and a method of venting exhaled gases.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Ms. Zita A. Yurko
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Respironics, Incorporated
Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

OCT 30 2009

Re: K090539
Trade/Device Name: BiPAP AutoSV Advanced
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: October 20, 2009
Received: October 21, 2009

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division 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 Advanced

The BiPAP AutoSV Advanced 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)

L Schultheiss

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

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