**TAB 3**

MAR 4 2009

# 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

**Official Contact**

Zita A. Yurko
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**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

**Predicate Device(s)** Respironics BiPAP AutoSV (K063540)

Respironics BiPAP Synchrony (K020777)

**Reason for submission** modified 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 AutoSV was cleared in K063540. The BiPAP Synchrony with Bi-Flex was cleared in K020777. Design verification tests were performed on the Respironics BiPAP AutoSV 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 2006.

**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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2009

Ms. Zita A. Yurko
Director, Regulatory Affairs
Respironics, Incorporated
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K090248
Trade/Device Name: BiPAP AutoSV
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: January 30, 2009
Received: February 2, 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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Ginette Y. Michaud, M.D.
Acting 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K980248