

TAB 5

MAY 8 2007

510(K) SUMMARY

Date of Submission 31 January 2007

Official Contact Zita A. Yurko
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Classification Reference 21 CFR 868.5895

Product Code MNS – Continuous ventilator

Common/Usual Name Ventilator, continuous, non-life supporting

Proprietary Name Respironics BiPAP Synchrony with AVAPS Ventilatory Support System

Predicate Device(s) Respironics BiPAP Synchrony HC (K992530)
Respironics BiPAP Synchrony S/T (K012323/K020777)

Reason for submission new device (built on an existing cleared device platform)

Substantial Equivalence

The BiPAP Synchrony with AVAPS 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. To establish a basis for effectiveness of the Average Volume Assured Pressure Support ventilation therapy feature, Resironics performed clinical study to assure therapy provided with AVAPS was equivalent to or better than existing therapy provided without AVAPS. Results from this study determined that AVAPS is as effective as that of therapy without AVAPS. Further, a risk analysis to identify the consideration of using the existing BiPAP Synchrony electromechanical platform with the Average Volume Assured Pressure Support Ventilation therapy feature to treat adult patients with OSA and Respiratory Insufficiency. To determine equivalence between the Resironics BiPAP Synchrony with AVAPS and the Resironics BiPAP Synchrony, 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. Bench testing has confirmed that the BiPAP Synchrony with AVAPS performs equivalently to the device predicate BiPAP Synchrony (K992530/K012323/K020777). All tests were verified to meet the required acceptance criteria.

Intended Use

The BiPAP Synchrony with Average Volume Assured Pressure Support (AVAPS) is intended to provide non-invasive ventilatory support to treat adult patients with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The Synchrony may be used in the hospital or home.

The Synchrony is intended for use with nasal masks and full-face masks as recommended by Resironics.

Environment of Use/Patient Population

For use in the home or hospital/institutional environment on adult patients.

Device Description

The Resironics BiPAP Synchrony with AVAPS 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 AVAPS feature is professionally selected and rides on top of the existing modality provided by the BiPAP Synchrony. The BiPAP Synchrony with AVAPS pressure control that contains various controls which are used to configure positive pressure therapies.

The BiPAP Synchrony with AVAPS 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 Synchrony with AVAPS 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 and a patient device (mask).

(End of Tab.)



MAY 8 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K070328
Trade/Device Name: BiPAP Synchrony with AVAPS
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: April 30, 2007
Received: May 1, 2007

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.

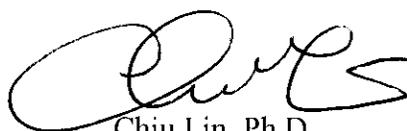
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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): K070328

Device Name: BiPAP Synchrony with AVAPS

Intended Use/Indications for Use

The BiPAP Synchrony with Average Volume Assured Pressure Support (AVAPS) is intended to provide non-invasive ventilatory support to treat adult patients with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The Synchrony may be used in the hospital or home.

The Synchrony is intended for use with nasal masks and full-face masks as recommended by Respironics.

Environment of Use/Patient Population

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

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PAGE IF NEEDED)

