# TAB 3

# 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

K092818

JAN 22 2010

**Official Contact**

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**Establishment Registration #** 2518422

**Classification Reference** 21 CFR 868.5895

**Product Code** MNS – ventilator, continuous, non-life supporting

**Common/Usual Name** Ventilatory Support System

**Proprietary Name** Respironics BiPAP AVAPS Ventilatory Support System

**Predicate Device(s)** Respironics BIPAP Synchrony 2 Ventilatory Support System (K071509)

Respironics REMstar Q Series Auto with AFLEX CPAP System (K091319)

**Reason for submission** Modified design.

## Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate devices:

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

Design verification tests were performed on the Respironics BiPAP AVAPS 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 d scribed 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 Respironics BiPAP AVAPS Ventilatory Support System is intended to provide non-invasive ventilatory support to treat adult and pediatric (> 7 years of age; > 40 lbs) patients with obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. BiPAP AVAPS Ventilatory Support System may be used in the hospital or home.

## Device Description

The Respironics BiPAP AVAPS Ventilatory Support System is a microprocessor controlled blower based positive pressure ventilatory system with integrated heated humidifier. The device platform being used as the key topic for this submission was previously cleared in K091319. The same ventilation modalities and therapy features, previously cleared in K071509 is also included in the BiPAP AVAPS Ventilatory Support System, which is the topic of this submission. These modes and therapy features include: CPAP, Spontaneous, Spontaneous/Timed, Timed, Pressure Control modes with Bi-Flex or AVAPS therapy features available if enabled by the health care professional.

A Graphical user interface displays device data and device settings.

The BiPAP AVAPS Ventilatory Support System 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.

Like its predicates, the BiPAP 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 tubing, an exhalation device, and a patient interface device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

JAN 22 2010

Re: K092818
Trade/Device Name: Respironics BiPAP AVAPS Ventilatory System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilators
Regulatory Class: II
Product Code: MNS
Dated: September 11, 2009
Received: October 26, 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

Anthony D. Watson, B.S., M.S., M.B.A.
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: Respironics BiPAP AVAPS Ventilatory System

The Respironics BiPAP AVAPS Ventilatory System is intended to provide non-invasive ventilatory support to treat adult and pediatric (> 7 years of age; > 40 lbs) patients with obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The Respironics BiPAP AVAPS Ventilatory System may be used in the hospital or home.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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: K092818