TAB 3

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Original Date of Submission	April 21, 2010
Device Trade Name	BiPAP Synchrony 2
	SEP 2 2010
Common/Usual Name	Ventilator, continuous, non-life supporting
Establishment Registration #	2518422
Official Contact / Address of Mfr. Facility	Zita A. Yurko Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-4120 FAX (724)-387-7490 CELL (724) 882-4120 Zita.Yurko@Respironics.com
Classification	Class II device
Classification Panel	Anesthesiology Devices
Classification Reference	21 CFR 868.5895
Product Code	MNS - Continuous ventilator
Predicate Device(s)	Respironics BiPAP Synchrony 2 Ventilatory Support System (K092043) Respironics Performax Total Face Mask (K072592) Respironics Spectrum 2 Full Face Mask (K002465)
Labeling	Draft Labeling can be found in Tab 5.
Intended Use	The Respironics BiPAP Synchrony 2 is intended to provide non-invasive ventilation for pediatric patients 7 years or older (> 40 lbs) or adult patients (> 66 lbs) with respiratory insufficiency or obstructive sleep apnea, in the hospital or home.
Reason for Submission	Include two additional Respironics pediatric full face masks to be used with this device. Device is unchanged as a result of the addition of either of these masks.

Substantial Equivalence

The BiPAP Synchrony 2 system has the following similarities to the previously cleared predicate device:

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

There is no change to the intended use, operating principle, technology or manufacturing process for the BiPAP Synchrony. Furthermore, there is no modification required to the electromechanical platform of the BiPAP Synchrony 2 as a result of adding additional Respironics pediatric masks to the existing cleared device (K092043). To demonstrate compatibility of the small size Respironics AF531 EE Leak 1 Full Face Mask (no built-in exhalation) and the small size Respironics AF531 EE Leak 2 Full Face Mask (with built-in exhalation) with the BiPAP Synchrony 2, mask compatibility testing was performed with each mask. This testing is provided in Tab 8 of this submission. This testing included pressure performance, waveform performance, triggering, cycling and alarm functionality testing. All tests were verified to meet the required acceptance criteria. Results of this testing concluded that the verification testing raises no new issues of safety or effectiveness by adding the small size of either of these full face masks to the cleared BiPAP Synchrony 2.

Respironics has followed the FDA's Guidance for Industry and FDA Staff document "pre-market assessment of pediatric medical devices" and applied the principle of FDA's Least Burdensome Approach to demonstrate the Substantial Equivalence of the BiPAP Synchrony 2 system. As a result, we conclude that the existing indications for use can be safely and effectively applied to this device with the small size of either the Respironics AF531 EE Leak 1 Full Face Mask or the Respironics AF531 EE Leak 2 Full Face Mask.

Intended Use

The Respironics BiPAP Synchrony 2 is intended to provide non-invasive ventilation for pediatric patients 7 years or older (> 40 lbs) or adult patients (>66 lbs) with respiratory insufficiency or obstructive sleep apnea, in the hospital or home.

Device Description

The Respironics BiPAP Synchrony 2 device is unchanged from K092043. The BiPAP Synchrony 2 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 only change to the Respironics BiPAP Synchrony 2 device is to include the small size Respironics AF531 EE Leak 1 Full Face Mask (no built-in exhalation) and the small size Respironics AF531 EE Leak 2 Full Face Mask (with built-in exhalation) as options for use by its pediatric users. These two masks consist of a silicon cushion, polycarbonate faceplate, and an integrated entrainment valve elbow made of polycarbonate with a silicone flapper. All of the materials used within these masks are predicate materials. The small size Respironics AF531 EE Leak 1 Full Face Mask has an entrainment elbow with no additional exhalation and will require a separate exhalation device. Whereas, the small size Respironics AF531 EE Leak 2 Full Face Mask has an entrainment elbow with built-in exhalation, negating the need for a separate exhalation device. Both masks are designed to be used with either the four point style headgear or the capstrap style headgear, allowing the patient an option.

Anthropometric analysis was performed on the small size of the Respironics AF531 EE Leak 1 Full Face Mask and the small size Respironics AF531 EE Leak 2 Full Face Mask. This analysis has determined that these two small masks will appropriately fit the pediatric population (> 7 years of age, > 40 lbs).

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

Respironics, Incorporated
C/O Ms. Zita A. Yurko
Director, Regulatory Affairs
Sleep & Home Respiratory Group
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

SEP 2 2010

Re: K101130
Trade/Device Name: BiPAP Synchrony 2
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: August 5, 2010
Received: August 10, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

K101130

Indications for Use

510(k) Number (if known): _____

Device Name: BiPAP Synchrony 2

The Respironics BiPAP Synchrony 2 is intended to provide non-invasive ventilation for pediatric patients 7 years or older (> 40 lbs) and adult patients (> 66 lbs) with respiratory insufficiency or obstructive sleep apnea, 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schaltmann

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

510(k) Number: K101130