TAB 3

K092043

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

AUG 0 5 2009

Original Date of Submission	30 June 2009
Device Trade Name	BiPAP Synchrony 2
Common/Usual Name	Ventilator, continuous, non-life supporting
Establishment Registration #	2518422
Address of Mfr. Facility	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-4120 FAX (724)-387-4216 CELL (724) 882-4120
Classification	Class II device
Classification Panel	Anesthesiology Devices
Classification Reference	21 CFR 868.5895
Product Code	MNS - Noncontinuous ventilator
Predicate Device(s)	Respironics BiPAP Synchrony 2 Ventilatory Support System (K063533/K071509) Respironics Performax Total Face Mask (K072592)
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 a 3rd Respironics pediatric total face mask to use with this device. Device is unchanged as a result of the addition of this mask

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. Further, there is no modification required to the electromechanical platform of the BiPAP Synchrony 2 as a result of adding a third Respironics pediatric mask to the existing cleared device (K063533/K071509). To demonstrate compatibility of the Respironics Performax Youth EE mask with the BiPAP Synchrony 2, mask compatibility testing was performed. 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.

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 new Respironics 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 K063533/K071509. The only change is to include the Respironics Performax Youth EE mask as a 3rd option for use by its pediatric users. This mask is the same mask design as is used by the small size of the cleared Respironics Performax Total Face Mask (K072592). The mask consists of a silicon cushion, polycarbonate faceplate with an

elbow that contains the exhalation feature. The anthropometric profile of the Respironics Performax Youth EE mask was designed to meet the 90th percentile for pediatrics age 7 and older and > 40 lbs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

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

AUG 0 5 2009

Re: K092043
Trade/Device Name: BiPAP Synchrony 2
Regulation Number: 868.5895
Regulation Name: Continuous Ventilators
Regulatory Class: II
Product Code: MNS
Dated: June 30, 2009
Received: July 6, 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/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

Susan Runner, D.D.S., M.A.
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 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)

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

510(k) Number: K092043