TAB 3

K071509
Page 1 of 2

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

AUG - 8 2007

Original Date of Submission	30 May 2007
Device Trade Name	BiPAP Synchrony 2 Ventilatory Support System
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) Respironics Reusable Contour Nasal Mask (K991648)
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 Respironics pediatric 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 BiPAP Synchrony 2 as a result of adding a Respironics pediatric mask to the existing cleared device (K063533). To demonstrate compatibility of the Respironics 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 safety 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. The only change is to include a Respironics pediatric mask as a second option for use by its pediatric users. This mask is the same mask design as is used by the cleared Respironics Reusable Contour Deluxe Nasal Mask (K991648). The mask consists of a silicon cushion, polycarbonate faceplate with an elbow that contains the exhalation feature. The anthropometric profile of the Respironics Pediatric Mask matches that of the Resmed Kidsta previously cleared in K063533.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2007

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

Re: K071509
Trade/Device Name: BiPAP Synchrony 2 Ventilatory Support System
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: July 6, 2007
Received: July 9, 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.

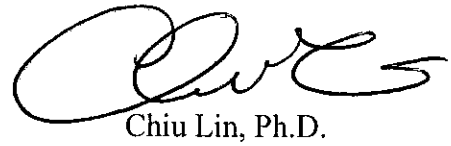
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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): _____

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) acting B.C.
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K071509