TAB 5

510(K) SUMMARY

FEB 2 0 2007

Date of Submission	20 November 2006
Official Contact	Zita A. Yurko Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Zita.yurko@respironics.com 724-387-4120 t 724-882-4120 c 724-387-4216 f
Classification Reference	21 CFR 868.5895
Product Code	MNS – Non-Continuous ventilator
Common/Usual Name	Ventilator, continuous, non-life supporting
Proprietary Name	Respironics BiPAP Synchrony 2 Ventilatory Support System
Predicate Device(s)	Respironics BiPAP Synchrony HC (K992530) Respironics BiPAP Synchrony S/T (K012323) Respironics BiPAP Harmony (K031656) Resmed VPAP III ST-A / Kidsta system (K060105)
Reason for submission	Include pediatric (7 years and older, > 40 lbs) indication.

Substantial Equivalence

The BiPAP Synchrony 2/ Kidsta system 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. The BIPAP Harmony was cleared in K031656 using the BiPAP Synchrony as the device predicate. The Mirage Kidsta was cleared in K060105. Respironics has performed a risk analysis to identify the additional considerations of using the BiPAP Synchrony 2 / Kidsta system on pediatric patients (> 7 years and > 40 lbs). Additional testing based on the BiPAP Synchrony 2 / Kidsta risk analysis was performed to ensure the safety and efficacy of the BiPAP Synchrony 2/ Kidsta system when used on the pediatric patient (> 7 years and > 40 lbs). Bench testing has confirmed that the BiPAP Synchrony 2 performs equivalently to the device predicate VPAP III ST-A (K060105). Additionally bench testing was performed to demonstrate compatibility of the Kidsta mask (K060105) with the BiPAP Synchrony. This testing included, pressure performance, waveform performance, triggering, cycling and alarm functionality testing. All tests were verified to meet the required acceptance criteria.

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/ Kidsta mask system to its predicate devices (Respironics BiPAP Synchrony, BiPAP Harmony and the VPAP ST-A/Kidsta mask system). We conclude that the existing and cleared adult indications for use can be safety and effectively applied to pediatric patients (> 7 years and > 40 lbs).

Intended Use

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

Device Description

The Respironics BiPAP Synchrony 2 Ventilatory Support System 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 BiPAP Synchrony 2 also has a CPAP mode in which a fixed pressure is delivered and four bi-level operating modes which determine how the changes between IPAP and EPAP pressures are made, Spontaneous, Spontaneous/Timed, Timed and Pressure Control.

The BiPAP Synchrony 2 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 2 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 the Mirage Kidsta mask (K060105).

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

FEB 2 0 2007

Re: K063533
Trade/Device Name: BiPAP Synchrony 2
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: November 20, 2006
Received: November 22, 2006

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.

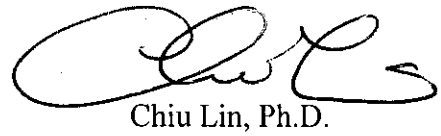
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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: K063533