DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2006

Dr. John O'Dea
General Manager
Respironics (Ireland) Limited
Parkmore Business Park,
Parkmore West
Galway, Ireland

Re: K053168
Trade/Device Name: BiPAP Focus
Regulation Number: 21 CFR 868.5895
Regulation Name: Ventilator, Continuous, Non-Life-Supporting
Regulatory Class: II
Product Code: MNS
Dated: November 10, 2005
Received: November 14, 2005

Dear Dr. O'Dea:

This letter corrects our substantially equivalent letter of January 4, 2006.

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 (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.

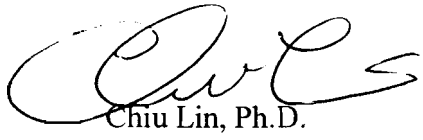
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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 continue 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/dsma/dsmamain.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

510(k) Number: _____ (To be assigned)

Device Name: BiPAP Focus

Indications for Use:

The BiPAP Focus ventilator is a non-invasive, pressure support ventilator used to augment the breathing of patients suffering from acute or chronic respiratory insufficiency, or respiratory failure, or to maintain airway patency and provide ventilatory support to patients who experience obstructive sleep apnea. It is not intended to provide the total ventilatory requirements of the patient.

Intended Population Adults > 30 kg

Environments of use Hospital, sub-acute and intra-hospital transport under qualified clinician direction and supervision

Prescription Use XX (Part 21 CFR 801 Subpart D) **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)

K053168

Non-Confidential Summary of Safety and Effectiveness
Page 1 of 2
10-Nov-05

Respironics Ireland Ltd.
Parkmore Business Centre
Parkmore West
Galway, Ireland

Tel - [353] (91) 709011
Fax - [353] (91) 758929

Official Contact: John O'Dea, Ph.D. – General Manager

Proprietary or Trade Name: BiPAP Focus

Common/Usual Name: Noninvasive ventilator

Classification Name: ventilator, continuous, minimal ventilatory support, facility use (MNT)

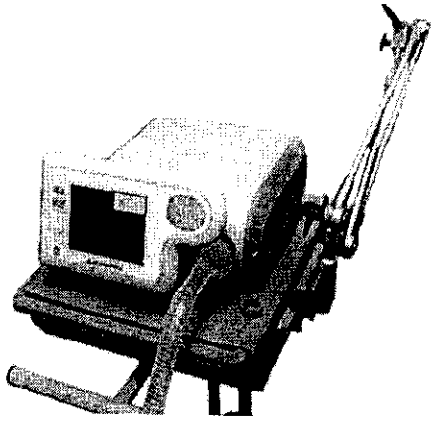
Device: Model - BiPAP Focus

Predicate Devices: Respironics – Vision – K982454
Harmony K984407 and K031656

Device Description:

The BiPAP Focus is a non-invasive ventilator which has two (2) ventilation modes:

1. Continuous positive airway pressure (CPAP) which provides a single level of positive pressure to the patient
2. Spontaneous/Timed (S/T) which provides two levels of positive pressure (one during inspiration - I_{PAP} and one during expiration – E_{PAP}) and delivers timed breaths if the patient does not initiate a breath.



Indications for use – The BiPAP Focus ventilator is a non-invasive, pressure support ventilator used to augment the breathing of patients suffering from acute or chronic respiratory insufficiency, or respiratory failure, or to maintain airway patency and provide ventilatory support to patients who experience obstructive sleep apnea. It is not intended to provide the total ventilatory requirements of the patient.

Non-Confidential Summary of Safety and Effectiveness
Page 2 of 2
10-Nov-05

Patient Population - For use with patients > 30 kg

Environment of Use - Home, Hospital, Sub-acute Institutions

Differences Between Other Legally Marketed Predicate Devices

The differences between the new device, BiPAP Focus, and the predicate devices are -

- An Internal battery and associated charging circuit is being added;
- The existing Buzzer on Harmony 2 will become the backup Buzzer;
- The existing Remote Alarm will be reconfigured to go through an internal relay to isolate the circuit. A ¼ Screen VGA will be used instead of the current LCD;
- The Alarm LEDs will be supplemented with Battery Status LEDs;
- The "Vent Inop" LED will be replaced by a High Priority Text based alarm; and
- The Industrial Design of the unit will cater for additional GUI circuitry.

The BiPAP Focus is viewed as having a non-invasive ventilation capability substantially equivalent to the following predicate devices –

Respironics – Vision – K982454 and Harmony K984407 and K031656

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.