K031656

JUL 30 2003

TAB 3

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact	Zita A. Yurko Manager, Regulatory Affairs/Product Assurance Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 724-387-4120 724-387-4206 (fax) Email: Zita.Yurko@Respironics.com
Classification Reference	21 CFR 868.5895
Product Code	MNS – Non-Continuous ventilator
Common/Usual Name	Ventilator, continuous, non-life supporting
Proprietary Name	Respironics BiPAP Harmony Ventilatory Support System
Predicate Device(s)	Respironics BiPAP Synchrony Ventilatory Support System (K012323) Respironics BiPAP BiPAP Pro Bi-Level System (K011714)
Reason for submission	Modified design, enhanced mode; change in environment of use.

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate devices:

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

Design verification tests were performed on the Respironics BiPAP Harmony Ventilatory Support System as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate devices.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices," May 1998.

Intended Use

The BiPAP Harmony is intended to provide non-invasive ventilation in adult patients (>30 kg) for the treatment of respiratory insufficiency (a condition in which the patient can continue without ventilation for some period, such as overnight) or obstructive sleep apnea. The BiPAP Harmony may be used in the home or hospital/institutional environments.

The BiPAP Harmony is intended for use with nasal masks and full-face masks as recommended by Respironics.

Device Description

The Respironics BiPAP Harmony Ventilatory Support System is a microprocessor controlled blower/valve based bi-level positive pressure system that delivers two different positive pressure levels (IPAP/EPAP). To improve comfort of the therapy being delivered, Respironics is adding an additional therapy feature to the CPAP and S modes only to provide pressure relief during exhalation. The BiPAP Harmony 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 a patient interface device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2003

Ms. Zita A. Yurko
Manager, Regulatory Affairs
Respironics, Incorporated
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K031656
Trade/Device Name: BiPAP Harmony Ventilator Support System
Regulation Number: 868.5895
Regulation Name: Non-Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: May 27, 2003
Received: May 28, 2003

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 (301) 594-4646. 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,

Patricia Cavanaugh for

Susan Runner, DDS, MA
Interim 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 (if known): K031656

Device Name: Respironics BiPAP Harmony Ventilatory Support System

Intended Use/Indications for Use

The BiPAP Harmony is intended to provide non-invasive ventilation in adult patients (>30 kg) for the treatment of respiratory insufficiency (a condition in which the patient can continue without ventilation for some period, such as overnight) or obstructive sleep apnea.

The BiPAP Harmony is intended for use with nasal masks and full-face masks as recommended by Respironics.

Environment of Use/Patient Population

For use in the home or hospital/institutional environment on adult patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number: K031656