TAB 10

510(K) SUMMARY

Official Contact / Address of Manufacturing facility

Zita A. Yurko
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Respironics Inc.
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Murrysville, PA 15668

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Proprietary Name	BiPAP Auto
Common/Usual Name	Ventilator, Non-Continuous (Respirator)
Classification Reference	21 CFR 868.5905
Classification	Class II
Appropriate Classification Panel	Anesthesiology
Product Code	BZD
Predicate Devices	Respironics BiPAP Pro 2 with Bi-Flex (K043607) Respironics REMstar Auto with C-Flex (K041010)
Reason for submission	Modified design

Substantial Equivalence

This premarket notification submission demonstrates that the BiPAP Auto is substantially equivalent to the combination of the Respironics BiPAP Pro 2 with Bi-Flex (K043607) and the Respironics REMstar Auto with C-Flex (K041010). Design modifications have been made to the BiPAP Pro 2 with Bi-Flex for this submission, including the incorporation of several REMstar Auto with C-Flex device features, to create the BiPAP Auto. None of the modifications affect the safety or effectiveness of the device.

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The following changes have been made:

- The Auto therapy algorithm present in the REMstar Auto with C-Flex CPAP System (K041010) has been added to the device to create the Auto Bi-level mode that automatically adjusts the IPAP and EPAP levels to meet the patient's needs.
- The Split Night mode (split night study feature) has been added to the device. The Split Night mode limits the pressure during the first portion of the night to allow diagnostic recording; thereafter the pressure responds to the patient's needs to provide an assessment of therapeutic requirements. The Split Night mode (split night study feature) is based on the Split Night Auto CPAP mode (split night study feature) currently cleared by the FDA in K041010 (REMstar Auto with C-Flex CPAP System).

Indications for Use

The BiPAP Auto ~~system~~ delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea ~~only.~~ The device is for use in the home or hospital/institutional environment on adult patients.

Device Description

The Respironics BiPAP Auto is a microprocessor controlled blower based bi-level positive pressure system that delivers two different 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. Two modes are being introduced, which include the Auto Bi-Level mode and Split Night Auto Bi-Level mode. Bi-Level therapy with automatically adjusting IPAP and EPAP levels is delivered in the Auto Bi-Level mode. The Split Night Auto Bi-Level mode limits the pressure during the first portion of the night to allow diagnostic recording; thereafter the pressure responds to the patient's needs to provide an assessment of therapeutic requirements. Pressure relief upon exhalation (Bi-Flex feature) may be enabled during Auto Bi-Level therapy.

The BiPAP Auto 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, an exhalation device, and a patient interface device.

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Performance testing

An extensive collection of tests has been conducted and successfully completed, including clinical efficacy, safety, performance and comparative tests. Declarations of conformance to the FDA Recognized list of consensus standards have been provided in support of the safety and effectiveness of the BiPAP Auto. This list of performance testing included in the submittal is as follows:

- **IEC 60601-1: 1988 + A1: 1991 + A2: 1995** Medical Electrical Equipment – Part 1: General Requirements for Safety
- **IEC 60601-1-2: 2001** Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and tests
- **ISO 10993-1: 1997** Biological Evaluation of Medical Devices – Evaluation and Testing
- **IEC 68-2-6: 1995** Environmental Testing - Part 2: Tests – Test Fc: Vibration (Sinusoidal)
- **IEC 68-2-27: 1987** Environmental Testing - Part 2: Tests - Test Ea and Guidance: Shock
- **IEC 68-2-34: 1993** Environmental Testing - Part 2: Tests - Test Fd: Random Vibration Wide Band
- Bench Testing – BiPAP Auto vs. REMstar Auto with C-Flex; assessed the event detection and control capability of the BiPAP Auto.
- System Design Verification Test Procedure/Report; assessed the features of the BiPAP Auto to ensure compliance with the system level requirements and assesses compliance of the BiPAP Auto to the Operational and Storage test conditions stated in the 1993 FDA Reviewers Guidance.
- Clinical Efficacy Study; demonstrated that the Auto Bi-Level Mode (auto-adjusting bi-level positive airway pressure) of the BiPAP Auto device is as effective at determining optimal pressures as manually titrated, bi-level positive airway pressure. The following performance indicators additionally demonstrate the clinical efficacy of the Auto Bi-Level therapy: Auto Bi-Level therapy maintains lower average treatment pressures (as defined by average IPAP and average EPAP as compared to manually titrated fixed pressure bi-level therapy), and the AHI will remain below 10 during polysomnography.

Additional testing has been performed to ensure safety & effectiveness of the BiPAP Auto. This testing involves the unit, module, and functional testing of the software of the device (firmware). Since we are able to declare compliance to ANSI/AAMI: SW-68:2001 Medical Device software – Software life cycle processes, these test protocols and reports are not required to be included as part of this submittal, but are available upon request. Additionally, the following set of standards and guidance documents have been used in the design of the BiPAP Auto. These include:

- ANSI/AAMI SW-68: 2001 Medical Device Software – Software Life Cycle Processes.
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 1998
- FDA Reviewer's Guidance General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002

- FDA Reviewer's Guidance (#G95-1, 5/1/95) Biological Evaluation of Medical Devices; Use of ISO-10993
- FDA Reviewer's Guidance for Premarket Notification Submissions, Appendix A, November 1993

Conclusion

It is the conclusion of Respironics that the BiPAP Auto is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns of safety or effectiveness.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2005

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

Re: K050759
Trade/Device Name: BiPAP Auto
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: May 17, 2005
Received: May 19, 2005

Dear Mr. 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.

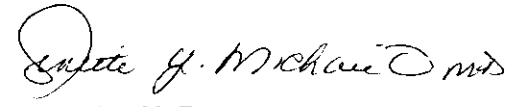
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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): K050759

Device Name: BiPAP Auto

Indications for Use:

The BiPAP Auto delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea. The device is for use in the home or hospital/institutional environment on adult patients.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Signature M.D.

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

510(k) Number: K050759