FEB - 1 2012



**Section 05: 510(k) Summary** K113053

**Administrative Information and Device Identification**

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|---|---|
| Name and address of the manufacturer and sponsor of the 510(k) submission: | Manufacturer:<br><br>Respironics, Inc.<br>312 Alvin Drive<br>New Kensington, PA 15068<br><br>Sponsor:<br><br>Respironics<br>1740 Golden Mile Highway<br>Monroeville, PA 15146<br>Office: 724-387-7562<br>Fax: 724-387-7490 |
| FDA registration number of the manufacturer of the new device: | 2518422 |
| Official contact person for all correspondence: | Elaine Larkin<br>Regulatory Affairs Engineer<br>Respironics<br>1740 Golden Mile Highway<br>Monroeville, PA 15146<br>Office: 724-387-5350<br>Fax: 724-387-7490<br>Email: elaine.larkin@philips.com |
| Submission Date | October 12, 2011 |
| Classification Reference | 21 CFR 868.5895<br><br>a) *Identification.* A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.<br><br>(b) *Classification.* Class II (performance standards). |
| Panel Code: | MNS – ventilator, continuous, non-life supporting |
| Classification Panel: | Anesthesiology |

| | |
|---|---|
| Common/Usual Name | Ventilatory Support System |
| Proprietary name of new device: | • Respironics BiPAP A30 Ventilatory Support System |
| Predicate Device Name(s) and 510(k) numbers: | • BiPAP C Series Ventilatory Support System (K092818)<br>• V60 Ventilator (K082660)<br>• ResMed Stellar 150/100 (K103167) |
| Reason for submission: | Device modifications and additional accessories |

# Intended Use

The BiPAP A30 Ventilator is intended to provide non-invasive ventilatory support to treat adult and pediatric patients weighing over 10kg (22lbs) with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. It is intended to be used in both the home and clinical settings, such as hospitals, sleep laboratories, sub-acute care institutions.

# Device Description

The Respironics BiPAP A30 Ventilatory Support System is a microprocessor controlled blower based positive pressure ventilatory system with integrated heated humidifier. The device platform being used as the key topic for this submission was previously cleared in K092818. The same ventilation modalities and therapy features, previously cleared in K071509 is also included in the BiPAP A30 Ventilatory Support System, which is the topic of this submission. These modes and therapy features include: CPAP, Spontaneous, Spontaneous/Timed, Timed, Pressure Control modes with Bi-Flex or AVAPS therapy features available if enabled by the health care professional.

A Graphical user interface displays device data and device settings.

The BiPAP A30 Ventilatory Support System 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.

Like its predicates, the BiPAP A30 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 tubing, an exhalation device, and a patient interface device.

**Performance Data**

Design and Verification activities were performed on the BiPAP A30 as a result of the risk analysis and product design requirements. All tests confirmed the product met the predetermined acceptance criteria. Performance testing comprises pressure performance, trigger and cycling, as well as volume assured pressure support ventilation. In addition to system verification testing, comparative testing was performed using common protocols for BiPAP A30 and the predicate device. The side-by-side testing demonstrated that the BiPAP A30 is Substantially Equivalent to the predicate devices.

This device has been tested to appropriate ISO and IEC standards and other applicable requirements passing all test protocols. The BIPAP A30 was designed and tested according to:

- IEC 60601-1:1988, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and its Amendments Al1:1991 and A2:1 995
- IEC 60601-1-2:2007, Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN ISO 8185 - Humidifiers for Medical Use - General Requirements for Humidification Systems
- ISO 10651-6:2004, Lung ventilators for medical use - Particular requirements for basic safety and essential performance. Part 6: Home care ventilatory support devices.

The new device complies with the applicable requirements referenced in the **FDA** guidance documents:

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical
- Devices (May 11, 2005)

## Non-Clinical Testing

This device has been tested to appropriate collateral and particular ISO, ASTM, and IEC standards and other applicable requirements passing all test protocols. The Respironics BiPAP A30 Ventilatory Support Systems was designed and tested according to guidance outlined in:

1. FDA Draft Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices (November 1993);
2. FDA Draft Reviewer Guidance for Ventilators July 1995; and
3. FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005).

## 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 A30 Ventilatory Support 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 2006.

## Conclusion:

Bench testing and comparative analysis has confirmed that the BiPAP A30 Ventilatory Support System performs equivalently to the cited predicate devices. The Respironics BiPAP A30 Ventilatory Support System is substantially equivalent to the predicate devices listed above and the device, as changed, does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration.
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Respironics, Incorporated
C/O Ms. Elaine Larkin
Engineer, Regulatory Affairs
Sleep & Home Respiratory Group
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

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Re: K113053
Trade/Device Name: BiPAP A30 Ventilatory Support System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: January 23, 2012
Received: January 25, 2012

Dear Ms. Larkin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Section 4.0 Indications for Use

### Indications for Use

510(k) Number (if known): _____

Device Name: BiPAP A30 Ventilatory Support System

The BiPAP A30 ventilator is intended to provide non-invasive ventilatory support to treat adult and pediatric patients weighing over 10 kg (22lbs) with Obstructive Sleep Apnea (OSA and Respiratory Insufficiency. It is intended to be used in both the home and clinical settings, such as hospitals, sleep laboratories, and sub-acute care institutions.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K113053