K121623



## Section 05: 510(k) Summary

DEC 14 2012

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| Name and address of the manufacturer and sponsor of the 510(k) submission: | Manufacturer:<br><br>Respironics, Inc.<br>1001 Murry Ridge Lane<br>Murrysville, PA 15668<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 |
| Date of Submission | 05/29/2012 |
| FDA registration number of the manufacturer of the new device: | 2518422 |
| Official contact person for all correspondence: | Joseph E. Olsavsky<br>Senior Manager, Regulatory Affairs, Home Respiratory Care<br>Respironics<br>1740 Golden Mile Highway<br>Monroeville, PA 15146<br>Office: 724-387- 7562<br>Fax: 724-387-7490<br>Email: joseph.olsavsky@philips.com |
| 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/Classification Name: | MNT – ventilator, continuous, minimal ventilatory support, facility use |
| Classification Panel: | Anesthesiology |

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| Common/Usual Name | Ventilatory Support System |
| Proprietary/Trade name of new device: | BiPAP A40 Ventilatory Support System |
| Predicate Device Name(s) and 510(k) numbers: | • BiPAP A30 Ventilatory Support System (K113053)<br>• Trilogy 200 Ventilatory Support System (K093416) |
| Reason for submission: | New Device |

**Intended Use**

The BiPAP A40 ventilator is intended to provide invasive and non-invasive ventilatory support to treat adulate and pediatric patients weighing over 10 kg (22 lbs) with Obstructive Sleep Apnea (OSA), Respiratory Insufficiency, or Respiratory Failure. It is intended to be used in the home, institutional/hospital, and portable applications such as wheelchairs and gurneys.

**Device Description**

The Respironics BiPAP A40 Ventilatory Support System is a microprocessor controlled blower and valve based positive pressure ventilatory system. The device can provide non-invasive or invasive ventilation. The device augments patient breathing by supplying pressurized air through a patient circuit. It senses the patients breathing effort by monitoring airflow in the patient circuit and adjusts its output to assist in inhalation and exhalation. This therapy is known as Bi-level ventilation. Bi-level ventilation provides a higher pressure, known as IPAP (Inspiratory Positive Airway Pressure), when you inhale, and a lower pressure, known as EPAP (Expiratory Positive Airway Pressure), when you exhale. The higher pressure makes it easier for you to inhale, and the lower pressure makes it easier for you to exhale. This device can also provide a single pressure level, known as CPAP (Continuous Positive Airway Pressure).

The BiPAP A40 Ventilator is compatible with the System One Heated Humidifier. The System One heated humidifier, previously cleared for use in K113053, is an accessory for the Philips Respironics A Series therapy devices to provide moisture to the circuit.

The BiPAP A40 ventilator introduces a new therapy mode called AVAPS-AE. This therapy mode combines an improved AVAPS algorithm with an auto-back up to treat hypoventilation. An auto-EPAP algorithm runs simultaneously with the bi-level therapy to deliver the pressure support at the optimal PEEP. Additionally the ventilator can be operated using AC power, a detachable battery, or an external battery.

A Graphical user interface displays device data and device settings.

The BiPAP A40 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 A40 Ventilatory Support System is intended for use with a patient circuit that is used to connect the device to the patient interface device (mask or trach). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen tubing, an exhalation device, and a patient interface device.

**Technological Characteristics Compared to Predicate**

The primary device platform being used as the key topic for this submission, the BiPAP A30 Ventilatory Support System was previously cleared in K113053. The same ventilation modalities and therapy features, previously cleared in K113053 are also included in the BiPAP A40 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 the AVAPS therapy features available if enabled by the health care professional.

The secondary device predicate, the Trilogy 200 was previously cleared in K093416. Similar to the Trilogy 200, the BiPAP A40 can provide pressure up to 40cm, provide invasive support if prescribed, be used in mobile applications such as wheelchairs, and provides an optional detachable battery.

Comparison of Device Technological Characteristics to Predicate Devices

The BiPAP A40 Ventilatory Support System has the following similarities to those predicate devices listed in this submission which previously received 510(k) concurrence; the BiPAP A40 ventilator:

- Has the same/similar intended use,
- Uses the same operating principle,
- Incorporates the same basic ventilator system requirements including, but not limited to: physical interfaces; visual, audible and remote alarm system; modes of operation; performance settings;
- Incorporates similar materials; and
- Uses the same manufacturing processes.

The table below summarizes the technical characteristics between the BiPAP A40 Ventilatory Support System to those that are similar to the predicate devices listed in the submission:

| **Technological Characteristic** | **Description** |
|---|---|
| Patient Population | Patients weighing over 10kg (22lbs) |
| Ventilation Type | Non Invasive or Invasive Support |
| Design | Microprocessor valve controlled DC blower motor design |
| Pressure Regulation Method | Pressure feedback, motor speed and valve |
| Modes of Operation | CPAP, Spontaneous / Timed, Spontaneous, Pressure Control, Timed |
| CPAP Pressure | 4 to 20 cmH2O |
| IPAP Pressure | 4 to 40 cmH2O for S, S/T, T and PC (IPAP Min / Max)<br>4 to 25 cmH2O for S mode with BiFlex enabled |
| EPAP Pressure | 4 to 25 cmH2O for S, S/T, T and PC (EPAP Min / Max)<br>4 to 20 cmH2O for S mode with BiFlex enabled |
| BiFlex | User settable parameter that has 3 flex settings and is enabled in S mode up to 25 cmH2O |
| AVAPS | Average volume assured pressure support available in S, S/T, PC and T modes |
| AVAPS Rate | 0.5 to 5 cmH2O / minute |
| Ramp | User settable; Linear time based |
| Rise Time | User settable parameter that has 6 settings; not available in CPAP mode |
| Inspiratory Time | 0.5 to 3.0 sec available in S/T, PC and T modes |
| Breath Rate | 0 to 40 bpm in S/T and PC modes<br>4 to 40 bpm in T mode |
| Triggering | AutoTrak and Flow Trigger |
| Pressure Accuracy | ± 2.5 cmH2O of the setting |
| Alarm / Power Control Panel Indicators | LED / Audible Alarm indicators<br><br>Two alarm LED indicators: Red High Priority and Yellow Low Priority |
| Adjustable Alarms | Patient Disconnect, Apnea Alarm, High Respiratory Rate, Low |

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| | minute ventilation and Low tidal volume alarm |
| System Error Alarms | Loss of power, Ventilator inoperative, Low Battery, Pressure regulation, Low Circuit Leak, High Temperature, AC Power Disconnect, Keypad Stuck, Replace Detachable Battery, Insert SD Card, Card Error Info message, Start on Battery Info Message, Check AC Power Supply Info message, Battery Disconnect Info message, Battery Discharging Stopped Due to Temperature, Battery not charging due to temperature, Battery not charging, Battery depleted and Detachable battery disconnected info message |
| Required FDA alarms based on FDA Reviewers Guidance for Ventilators | Loss of main power supply, Breathing circuit integrity, High airway pressure and Alarm Battery Power Supplies |
| Humidifier Interface | The base unit and humidifier are connected through a hardwire connection and the base unit contains the control circuitry necessary for the operation of the humidifier. Setting controls reside on the base unit. |
| Humidifier Chamber and Volume | Polycarbonate chamber with stainless steel heater plate; 325ml volume |
| Remote Data Access | A secure digital (SD) card provides means for data access and/or serial communications. |

The modifications to the Respironics BiPAP A40 Ventilatory Support system that are the subject of this Abbreviated 510(k) submission consist of the following:

1. IPAP Pressure of 40 cmH2O pressure is comparable to the cited device predicates. The BiPAP A30 provides up to 30 cmH2O whereas the Trilogy 200 device provides up to 50 cmH2O

2. AVAPS AE Mode, which incorporates the existing cleared AVAPS therapy feature and adjusts EPAP based on upper airway resistance and incorporates an automatic back-up rate algorithm. This mode is comparable to the cited device predicates which both offer AVAPS therapy feature. The EPAP adjustments and auto back-up rate algorithm have been validated using non-clinical tests and have been determined to be substantially equivalent.

3. Detachable Battery Accessory includes the detachable battery module, Li-Ion battery and operating instructions. The Detachable Battery accessory is comparable to the cited device predicate, Trilogy 200. The same detachable battery is used for both devices.

4. Added invasive system one resistance to increase sensitivity of circuit disconnect alarm to ensure accuracy of the alarm when used with a high resistance circuit, which is similar to the Trilogy 200 alarm system.

5. Trigger Type Options available on the BiPAP A40 device include AutoTrak, Sensitive AutoTrak and Flow Trigger. AutoTrak and Flow Trigger are cleared on the device predicate, BiPAP A30 and Trilogy 200. Sensitive AutoTrak allows each algorithm to run

independently in order to more accurately detect a patient trigger in certain cases. Sensitive AutoTrak is an extension of the currently cleared AutoTrak.

6. Labeling Update to remove the current warning, "*The AVAPS and Bi-Flex features are for adult patients only*" from the User Manual for the BiPAP A40 device. There is adequate supporting literature for the use of Bi-Flex and AVAPS in the pediatric population weighing over 10kg.

**Performance Data**

Design and Verification activities were performed on the BiPAP A40 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 A40 and the predicate device. The side-by-side testing demonstrated that the BiPAP A40 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 A40 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 A11:1991 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 A40 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).

Performance testing was conducted for the BiPAP A40 device using side-by-side bench testing methodologies to demonstrate that the BiPAP A40 performs to design input specifications. Bench testing for the BiPAP A40 device was conducted using both closed-loop and open-loop applications from patient test cases to verify that the BiPAP AVAPS AE algorithm performs to specification. Bench testing conducted for the BiPAP A40 device characterized the types of worst-case scenario inputs that would be experienced in the intended use environment such as extreme flow rates, functional sensor malfunction, inaccuracy or complete sensor drop out and successfully demonstrated that the BiPAP A40 system responded safely under these conditions. The BiPAP A40 testing showed the device functions safely and effectively under worst case clinical scenarios (i.e. providing adequate pressure to maintain patent airway for a patient and avoiding over pressurization under defined clinical scenarios. The device adjusted to inter as well as intra patient variability.

Stability and safety of the AVAPS-AE algorithms is established by exception handling in the software to account for extreme flow rates or other cases which may otherwise cause unintended outputs. Bench test data demonstrated the algorithm's ability to safely change pressure support to maintain a target tidal volume in response to varying lung conditions. These changing lung conditions may be inter as well as intra patient variability. The bench test data demonstrated the algorithm's ability to safely adjust the EPAP setting within the prescription settings of EPAP

minimum and maximum in response to changes in upper airway resistance. These changing resistances may be inter as well as intra patient variability. The algorithm monitors the patient's spontaneous breath rate during therapy and sets a target backup rate below the patient's spontaneous rate. The algorithm reset accounts for variable breath rates from patient to patient.

**Adverse Event Summary Information**

The cited device predicate for the electro-mechanical (EM) device platform used for this submission is unchanged from the original clearance of the BiPAPA30 device (K113053). To date, there are no adverse events histories for this device platform in the Maude Database. A search of the Maude Database for **Product Code:** *cbk* **Brand Name:** *Trilogy* **Report Date From:** *01/01/2000* **Report Date To:** *03/31/2012* resulted in 8 records.
Of the 8 records, none were identified as being related to the EM platform of the BiPAP A40 device.

**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 A40 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, bench testing and comparative analysis has confirmed that the BiPAP A40 Ventilatory Support System performs equivalently to the cited predicate devices. The indications for use, technological characteristics, and principles of operation are similar to the predicate devices.

The modifications that are the subject of this 510(k) submission have been validated using non-clinical tests and have been determined to be substantially equivalent. The Respironics BiPAP A40 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 Center – WO66-G609
Silver Spring, MD 20993-002

December 14, 2012

Mr. Joseph E. Olsavsky
Senior Manager, Regulatory Affairs
Respironics, Incorporated
1740 Golden Mile Highway
MONROEVILLE PA 15146

Re: K121623
Trade/Device Name: BiPAP A40 Ventilatory Support System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNT
Dated: November 9, 2012
Received: November 13, 2012

Dear Mr. Olsavsky:

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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, 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): K121623

Device Name: BiPAP A40 Ventilatory Support System

The BiPAP A40 ventilator is intended to provide invasive and non-invasive ventilatory support to treat adult and pediatric patients weighing over 10 kg (22 lbs) with Obstructive Sleep Apnea (OSA), Respiratory Insufficiency, or Respiratory Failure. It is intended to be used in the home, institutional/hospital, and portable applications such as wheelchairs and gurneys.

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)

Albert E. Moyal 2012.12.14 11:05:59 -05'00' for LS

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

**510(k) Number:** _____