Section 04: 510(k) Summary

OCT - 4 2011

Administrative Information and Device Identification

Name and address of the manufacturer and sponsor of the 510(k) submission:	Manufacturer: Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Sponsor: Respironics 1740 Golden Mile Highway Monroeville, PA 15146 Office: 724-387-7562 Fax: 724-387-7490
FDA registration number of the manufacturer of the new device:	2518422
Official contact person for all correspondence:	Elaine Larkin Regulatory Affairs Engineer Respironics 1740 Golden Mile Highway Monroeville, PA 15146 Office: 724-387-5350 Fax: 724-387-7490 Email: elaine.larkin@philips.com
Classification Reference	21 CFR 868.5895 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. (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 Ventilator Series Oximetry

	Interface Kit
Predicate Device Name(s) and 510(k) numbers:	1. Respironics BiPAP AVAPS with Oximetry Module (K102465) 2. Respironics BiPAP AVAPS Ventilatory Support System (K092818)
Reason for submission:	Device modifications and additional accessories

Intended Use

The Oximetry Interface Kit can be used with Respironics BiPAP C-Series (BiPAP AVAPS and BiPAP S/T) ventilators to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate for adult and pediatric patients. The oximetry module may be used in a hospital or home care environment.

The Philips Respironics BiPAP C-Series Ventilatory System (BiPAP AVAPS and BiPAP S/T) is intended to provide non-invasive ventilatory support to treat adult and pediatric (> 7 years of ages; > 18 kg) patients with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The Respironics BiPAP C-Series Ventilatory Support System may be used in the hospital or home.

Device Description

The Respironics BiPAP C-Series (BiPAP AVAPS and BiPAP S/T) Ventilatory Support Devices when used with the Respironics Link Module Oximetry Interface Kit provides access to patient therapy information through the two-way transfer of data between patient devices and clinicians through the appropriate software including therapy efficacy and device settings as requested by the attending physician.

The intended use for the BiPAP C Series Ventilatory Support System is as follows: (K092818)

The Respironics BiPAP C-Series Ventilatory Support System (BiPAP AVAPS and BiPAP S/T) is intended to provide non-invasive ventilatory support to treat adult and pediatric (> 7 years of age; > 40 lbs) patients with obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The Respironics BiPAP C-Series Ventilatory Support System may be used in the hospital or home.

Both intended uses include information regarding the functionality, environments of use and target patient populations. The indications for use from K092818 remain unchanged. Lastly, the intended use for the BiPAP C Series device is provided in both the patient and provider manuals.

The Software modifications made to the Respironics BiPAP C-Series (BiPAP AVAPS and BiPAP S/T) Ventilatory Support Device, which is the subject of this submittal, allows the transfer of data from the Oximetry Interface Kit to the device display and SD card.

The Oximetry Interface Kit consists of the following components:

- Respironics Link Module – The Link Module is a communication accessory that attaches to the Ventilatory Support System. The Link Module provides the interface between the ventilator and the oximetry module. (Unchanged from K102465)
- SD Card and Mailer – The SD Card is a portable memory card that carries information from one data transfer device to another. In this system, the SD card is used to record therapy and compliance information from the therapy device and the oximetry module for use by the Encore Pro and/or DirectView patient data management software. (Unchanged from K102465)
- Masimo Oximetry Module and Sensor - The Masimo module, cable and sensor provides a non-invasive measurement of the oxygen saturation levels of hemoglobin. Data from the oximeter is transferred to the Ventilatory Support System via the Cable. This data is stored on the SD card in the ventilator for use by Encore Pro and/or DirectView patient data management software. (K041815, K090662, K012992, and K053269)

When connected to the flow generator, the oximetry module records treatment and pulse oximetry data during therapy. The data is stored on a secure digital card. After treatment, the secure digital card containing the data can be removed from the device and sent to the clinician for review.

The Respironics BiPAP C-Series (BIPAP AVAPS and BiPAP S/T) devices, cleared under K092818, when used with the Respironics Oximetry Interface Kit are microprocessor controlled blower based positive pressure systems that interface with an with integrated heated humidifier, like the predicate cleared in K102465.

The Respironics BiPAP C-Series Ventilatory Support System when used with the Respironics Oximetry Interface Kit continues to deliver Continuous or Bi-level Positive Airway Pressure support. All therapy modes and features are unchanged from the previously cleared device, K092818/K102465.

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 Oximetry Interface Kit when used with the BiPAP C-Series (BiPAP AVAPS and BiPAP S/T) 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 C-Series Ventilatory Support System with Respironics Oximetry Interface Kit 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.

Statement of Safety and Effectiveness

Based on the analysis for the comparison of design, function and features of the Respironics BiPAP C-Series (BiPAP AVAPS and BiPAP S/T) Support Systems use with Oximetry Interface Kit with the previously cleared Masimo sensors to the Respironics BiPAP AVAPS with Oximetry Module (K102465) and the Respironics BiPAP AVAPS device (K092818) together with the results of the functional and performance testing being able to demonstrate the device to be substantially equivalent to the predicate devices in terms of meeting performance criteria and functioning as intended, the device is determined to be substantially equivalent to the predicate devices listed in this summary and the device, as modified, does not raise any new issues of safety and effectiveness. The summary of testing is provided below.

Test Execution Summary

Please refer to Appendix D for detailed results.

ER#2206480, Time Meters – The purpose of this test is to verify that the Time Meters are recording time to the proper granularity, the accumulated time is viewable on the display, the time may be reset from the User Interface where permitted, and that the accumulated time is not lost when the unit is powered off. The accuracy of the Machine Time Meter and Blower Time Meter will be verified in real time, to the extent practical during the testing window, by this test. (Other Test Procedures will verify that the Time Meters may be viewed and/or cleared via the serial interface.)

ER#2206482, Standard Regression Test – This is a confidence test to be run with each new release of software. It exercises the most commonly-used features, to assure that no unexpected problems have been introduced.

ER#2209038, Pulse Oximetry User Interface – The purpose of this set of Test Cases is to verify that the new additions made to the User Interface to support the external Pulse Oximetry unit are all functional and that they have not introduced any unintended consequences.

ER#2209038, Pulse Oximetry Logging – The purpose of this set of Test Cases is to verify that the new Pulse Oximetry Log is being created and populated in accordance with the requirements. Different lengths of Therapy Sessions will be executed while a Pulse Oximetry unit is connected to verify that the expected Oximetry data was logged. The Pulse Oximetry unit will be connected without any SD Card and the Pulse Oximetry unit will be disconnected and reconnected to verify that each of those situations is managed.

ER#2209038, Serial Port AutoBaud Detection – The purpose of this Test Case is to verify that the Yoda Device is able to detect whenever a Pulse Oximetry unit that is sending data at 9600 baud is connected to the serial port and automatically adapt to that speed. It further verifies that it will similarly detect whenever there is a modem or a PC Direct connection that is sending data at 19,200 baud is connected to the serial port and automatically adapt to that speed.

ER#2209039, User Interface – Monitor Parameters Submenu – The purpose of this set of Test Cases is to verify that the new Monitor Parameters Submenu that has been added to the User Interface to display various calculated parameters on a common display panel is fully functional and that this addition has not introduced any unintended consequences.
Though a number of defects were found during testing, all issues have been addressed and either found to be resolved during subsequent retesting or found to be non-reproducible, with the exception of one defect (#222). All tests have passed and requirements referenced in these tests have been verified.

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

Ms. Elaine Larkin
Regulatory Affairs Engineer
Philips Respironics, Incorporated
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

OCT - 4 2011

Re: K111378
Trade/Device Name: BiPAP Ventilator Series Oximetry Interface Kit
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: September 19, 2011
Received: September 20, 2011

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.

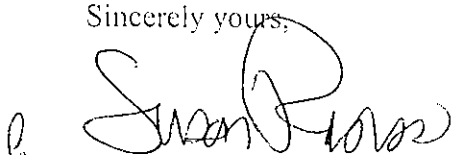
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 6.0 Indications for Use

Indications for Use

510(k) Number (if known): K111378

Device Name: BiPAP Ventilator Series Oximetry Interface Kit

The Oximetry Module can be used with Philips Respironics BiPAP C Series (BiPAP AVAPS and BiPAP S/T) ventilators to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate for adult and pediatric patients. The Oximetry module may be used in a hospital or home care environment.

The Philips Respironics BiPAP C-Series Ventilatory System (BiPAP AVAPS and BiPAP S/T) is intended to provide non-invasive ventilatory support to treat adult and pediatric (> 7 years of ages; > 18 kg) patients with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. The Respironics BiPAP C-Series Ventilatory Support System may be used in the hospital or home.

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)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111378