510(k) Summary

MAR 2 4 2011

Administrative Information and Device Identification

Name and address of the manufacturer and sponsor of the 510(k) submission:	Manufacturer: Philips Respironics 1001 Murry Ridge Lane Murrysville, PA 15668 Fax: (724) 387-4216 Sponsor: Philips 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 Philips 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:	Philips Respironics BiPAP C Series (BiPAP AVAPS – BiPAP S/T) with Oximetry Module System
Predicate Device Name(s) and 510(k) numbers:	1. Respironics BiPAP AVAPS Ventilatory Support System (cleared under K092818 – date of concurrence: January 22, 2010). 2. DeVilbiss DV5M SmartLink System (cleared under K082209 – date of concurrence: October 28, 2008). 3. Resmed S7 Elite and AutoSet Spirit CPAP Systems with ResLink (cleared under K024191 – date of concurrence: July 7, 2003).
Reason for submission:	Device modifications and additional accessories

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 AVAPS C Series 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 d scribed 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. (See Section 8.0 Substantial Equivalence Discussion of the original submittal, K102465)

Intended Use

The Nonin Xpod Oximetry Module can be used with Philips Respironics BiPAP C Series therapy devices (BiPAP AVAPS and BiPAP S/T) 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 Respironics BiPAP C Series Ventilatory System 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 System may be used in the hospital or home.

Device Description

The BiPAP AVAPS C Series device with Oximetry 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 setting as requested by the attending physician.

The Respironics Oximetry Module is designed for use with Respironics BiPAP AVAPS C Series and Respironics BiPAP S/T C Series flow generators to help the clinician monitor the end user's sleep and ensure that optimal treatment is provided.

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.

Both Respironics BiPAP C-Series with Oximetry Module devices are microprocessor controlled blower based positive pressure systems with integrated heated humidifier, like the predicate cleared in K092818. The Respironics BiPAP C-Series System with Oximetry Module also delivers two positive pressure levels (IPAP/EPAP), like the predicate cleared in K092818. The dual pressure levels provide a more natural means of delivering pressure support therapy to the patient resulting in improved patient comfort. In addition, the BiPAP C-Series System includes CPAP mode in which a fixed pressure is delivered. Four bi-level operating modes, S, S/T, T & PC, are also offered which determine how the changes between IPAP and EPAP pressure are made. All therapy modes are unchanged from the previously cleared K092818.

A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters. The therapy device will provide the following indications as to the status of the Oximetry module.

The BiPAP C-Series with Oximetry 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. (Unchanged from K092818) These alarms are specific to the ventilator and are not related to oximetry measurements.

Like its predicates, the BiPAP C-Series with Oximetry 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 19mm tubing, an exhalation device, and a patient interface device.

Device Modifications:
Modifications to the BiPAP AVAPS and BiPAP S/T C Series Ventilatory devices consist of the following:

- Revised labeling (Refer to the request for Additional Information Packet 1, Attachment A)
- Updated BiPAP C Series software to enable the flow generator and Link module to communicate and to provide additional display messages of the flow generator LCD to provide feedback to the use on correct connection of the Link Module
- Inclusion of the Oximetry Module System (used as an accessory to the previously cleared BiPAP C Series Devices, K092818) is a device designed for use with BiPAP C Series Devices to aid the clinician/provider in monitoring oximetry data during therapy. The data is

displayed real time and stored on a memory card (SD Card). The SD Card containing the data can be removed from the Oximetry Module System device and sent to a clinician/provider for review.

The Oximetry Module System consists of the:

- Nonin® Xpod® Oximeter Cable
- Nonin® Oximeter Sensor
- Philips Respironics Link Module
- Carrying Case
- SD Card and Mailer

• **Link Module** is a communication device that attaches to the BiPAP C Series device and collects oximetry data. The module transfers information to and from the Nonin oximeter sensor and the device via a data card and card reader.

• **SD Card** is a portable memory card that carries information from one data transfer device to another. In this system, the data card is a Secure Digital (SD) card that carries therapy information between the Link module on the BiPAP C Series device and the Encore and Direct View Series software.

• **Nonin Oximetry cable and sensors** provide a non-invasive measurement of the oxygen saturation levels of hemoglobin.

The BiPAP C Series device with Oximetry Module System provides access to patient therapy information through the two-way transfer of data between patient devices, the Link Module and both Encore and DirectView Patient Management Software (patient data management software).

Non-Clinical Testing:

This device has been tested to appropriate ISO, ASTM, and IEC standards and other applicable requirements passing all test protocols. The Respironics BiPAP C-Series with Oximetry System was designed and tested according to guidance outlined in:

1. FDA's Draft Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices (November 1993);

2. FDA's 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).

As suggested by FDA's November 1993 publication entitled "Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch;

Division of Cardiovascular, Respiratory, and Neurological Devices" the Respironics BiPAP C-Series with Oximetry System was tested in accordance with the applicable voluntary standards. The BiPAP C-Series with Oximetry System met the required performance criteria and functioned as intended.

See Section 16.7 Traceability Analysis provided with the original submittal (K102465), Response # 2, Verification and Validation Testing Documentation, included with this request for additional information packet, Section 9.3 Electromagnetic Compatibility and Electrical Safety provided with the original submittal (K102465), and Attachment A – BiPAP C-Series with Oximetry System Product Requirements Document provided with the original submittal (K102465).

Statement of Safety and Effectiveness:

Analysis of comparison of design, function and features of the BiPAP C-Series with Oximetry System to the Respironics BiPAP AVAPS device (K092818), the DeVilbiss DV5M SmartLink System (K082209) and ResMed S7Elite and AutoSet Spirit CPAP Systems with ResLink (K024191); together with the results of testing demonstrates the device to be substantially equivalent to the predicate devices in terms of meeting performance criteria and functioning as intended.

Conclusion:

The Respironics BiPAP C-Series with Oximetry System is substantially equivalent to the predicate devices listed in this Summary 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

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

MAR 24 2011

Re: K102465
Trade/Device Name: BiPAP AVAPS with Oximetry Module
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: March 18, 2011
Received: March 21, 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): _____

Device Name: BiPAP AVAPS with Oximetry Module

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

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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)

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

510(k) Number: K102465