K034032

MAR 16 2004

16 510(k) SUMMARY

Company Information:	Respironics, California Inc. 2271 Cosmos Court Carlsbad, CA. 92009
Contact Information:	Mary Funk Regulatory Affairs Project Manager Phone Number: (760) 918-7328 Fax Number: (760) 918-0169
Date Prepared:	December 3, 2003
Product Name:	PLV Continuum II Ventilator
Product Code:	73 CBK; 73 NOU
Common Name:	Ventilator
Classification:	Class II Continuous Ventilator (per 21 CFR 868.5895)
Predicate Devices:	• Respironics PLVC Ventilator K022750 • Respironics Esprit Ventilator K981072 • Pulmonetics LTV 1000 Ventilator K984056 • NPB Achieva Ventilator K990177

16.1 Device Description:

The PLV Continuum ventilator is a microprocessor controlled, compressor-based, mechanical ventilator. It is intended to control or assist breathing by delivering room air to the patient. PLV Continuum utilizes an internal compressor to generate compressed air for delivery to the patient. Breath delivery is controlled by software algorithms. The user interface on PLV Continuum has a membrane keypad with indicator Light Emitting Diodes (LED) for the selection and acceptance of patient settings and for the display of alarm conditions. PLV Continuum is capable of providing the following types of ventilatory support:

- Positive Pressure Ventilation, delivered either invasively (via endotracheal or tracheostomy tube) or non-invasively (via mask or mouthpiece).
- Assist/Control, Spontaneous Intermittent Mandatory Ventilation (SIMV) or Continuous Positive Airway Pressure (CPAP) modes of ventilation.
- Volume-Controlled (VC). Available in A/C and SIMV.
- Pressure-Controlled (PC). Available in A/C and SIMV.
- Pressure Support (PS). Available in SIMV and SPONT.

16.2 Intended Use:

The intended use of the PLVC II is to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The intended patient population includes pediatric and adult patients who weigh at least 5 kg (11 lbs). The PLV Continuum ventilator is intended for use in home, institutional and portable settings and may be used for invasive as well as non-invasive ventilation.

PLVC is not intended for use as an emergency transport ventilator. It is not intended for use in the presence of flammable anæsthetics. PLVC is a prescription use device that is intended for sale by or on the order of a physician.

16.3 Technological Characteristics:

Like other continuous ventilators, PLVC II utilizes an internal compressor to generate compressed air for delivery to the patient. Breath delivery is controlled by software algorithms that are equivalent to those used on the currently marketed Respironics PLV Continuum ventilator (K022750). PLVC II does not incorporate any new technological characteristics.

16.4 Determination of Substantial Equivalence:

The modes of ventilation on PLVC II are the same as the current PLVC, K022750 as well as other currently marketed ventilators. PLVC II has similar performance characteristics to the predicate devices with the same intended use, the same environment of use and patient populations. The PLVC II labeling and instructional information, including warning and caution statements, is standard for critical care ventilators used in institutional and home care environments.

16.5 Summary of Performance Testing:

Performance testing was conducted per the applicable sections of ASTM F 1100-90 and F 1246-91. EMC testing was performed per IEC 60601-1-2. Electrical, mechanical and environmental testing was performed in accordance with the "FDA Draft Reviewer Guidance for Premarket Notification Submissions" (1993). Software validation testing was performed per FDA's "Guidance for the Content of Premarket Submissions for Software contained in Medical Devices" (1998). The results of all testing demonstrate that all design and system requirements for the modified PLV Continuum have been met.

16.6 Conclusion:

The technological characteristics of the modified PLV Continuum ventilator and the results of the performance testing do not raise new questions of safety and effectiveness when compared to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2004

Ms. Mary Funk
Regulatory Affairs Project Manager
Respironics, California Incorporated
2271Cosmos Court
Carlsbad, California 92009-1517

Re: K034032
Trade/Device Name: PLV Continuum II Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: NOU, CBK
Dated: December 26, 2003
Received: December 29, 2003

Dear Ms. Funk:

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.

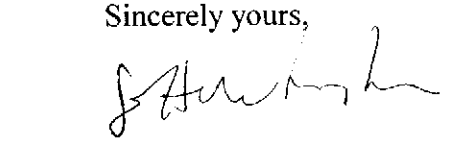
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,



for, 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 Statement

Applicant: Respironics California, Inc.
2271 Cosmos Court
Carlsbad, CA 92009
USA

510(k) Number: K034032

Device Name: PLV Continuum II

Indications for use: The intended use of the PLV Continuum II ventilator is to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The intended patient population includes pediatric and adult patients who weigh at least 5 kg (11 lbs). The PLV Continuum II ventilator is intended for use in home, institutional and portable settings and may be used for invasive as well as non-invasive ventilation.

Prescription Use: Yes (Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

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

510(k) Number K034032

Prescription Use _____ or OTC Use _____