K102985

APR - 5 2011

510(k) Summary

[Refer to 21 CFR 807.92]

Owner:	Respironics California, Inc. 2271 Cosmos Court Carlsbad, CA 92011
Contact Person:	Tamatha Ley Regulatory Affairs Specialist Phone: (760) 918-1026 Fax: (760) 918-0169
Date Prepared:	October 01, 2010
Proprietary Name:	V60 Ventilator with Proportional Pressure Ventilation and Auto-Trak+ Software Options
Common Name:	Ventilator
Classification Name:	Continuous Ventilator (21 CR 868.5895, Product Code 73 MNT)

Predicate Devices:	**Manufacturer**	**Device Name**	**510(k) Number**
	Respironics California, Inc.	V60 Ventilator	K082660

Intended Use of the Device:
The V60 Ventilator with Proportional Pressure Ventilation (PPV) and Auto-Trak+ Software Options is an assist ventilator and is intended to augment patient breathing. It is intended for spontaneously breathing individuals who require mechanical ventilation: patients with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea in a hospital or other institutional setting under the direction of a physician.

The ventilator is intended to support pediatric patients weighing 20 kg (44 lbs) or greater to adult patients. It is also intended for intubated patients meeting the same selection criteria as the noninvasive applications. The ventilator is intended to be used by qualified medical professionals, such as physicians, nurses, and respiratory therapists.

The ventilator is intended to be used only with various combinations of Respironics recommended patient circuits, interfaces (masks), humidifiers and other accessories.

Device Description:
The V60 Ventilator is a microprocessor controlled, electrically powered, mechanical ventilator.

The modifications to the currently marketed V60 Ventilator are two-fold; addition of PPV and Auto-Trak+ Software Options.

PPV is an assist mode of ventilation. It combines patient- triggered breaths that deliver pressure in proportion to patient effort. PPV provides ventilation support similar to that of the V60 Ventilator, specifically the S/T mode.

Auto-Trak+ is a Software Option that provides the clinician the means to adjust the trigger and cycle thresholds while retaining the functionality of Auto-Trak Sensitivity.

Substantial Equivalence: The addition of the PPV and Auto-Trak+ Software Options does not alter the fundamental scientific technology of the V60 Ventilator.

The V60 Ventilator with PPV and Auto-Trak+ Software Options has the same intended use as the currently marketed V60 Ventilator and similar design and technological characteristics as the other standard, currently marketed ventilators.

The V60 Ventilator with PPV and Auto-Trak+ Software Options installed is similar to the existing unmodified V60 Ventilators in that the technological characteristics with respect to the control mechanism, operating principle, energy type, ergonomics of the patient interface, firmware, environmental specifications, hardware and performance specifications remain unchanged.

All software activities, including verification and validation have been successfully completed in accordance with Respironics California, Inc. policies and procedures and the FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices dated May 11, 2005.

Bench testing has been successfully completed and waveform data, performed to ASTM F1100-90, comparing the V60 Ventilator with PPV and Auto-Trak+ Software Options with the currently marketed V60 Ventilator are contained in the submission.

In addition to the software verification and validation activities and performance testing, a comparison of performance characteristics has been conducted and documented in this submission.

Collectively, the results of the aforementioned activities support the assertion that the V60 Ventilator with PPV and Auto-Trak+ Software Options is substantially equivalent to currently marketed devices previously cleared by the FDA and these changes do not raise any new questions regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Re: K102985
Trade/Device Name: V60 Ventilator with Proportional Pressure Ventilation and Auto-Trak+ Software Options
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNT
Dated: March 30, 2011
Received: March 31, 2011

Dear Ms. Ley:

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 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

Indications for Use

510(k) Number (if known):

Device Name: V60 Ventilator with Proportional Pressure Ventilation and Auto-Trak+ Software Options

Indications for Use:
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Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801, Subpart D) (Part 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 and Dental Devices
510(k) Number: k102985