A. K110795

AUG 19 2011

510(k) Summary

[Refer to 21 CFR 807.92]

Owner:	Respironics California, Inc. 2271 Cosmos Court Carlsbad, CA 92011
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Application Correspondent:	Bob Marshall Director, Regulatory & Quality Engineering Regulatory & Quality Solutions, LLC Phone: (724) 327-0230 x105
Date Prepared:	July 1, 2011
Proprietary Name:	V200 Ventilator with IntelliTrak Option
Common Name:	Ventilator
Classification Name:	Continuous Ventilator (21 CR 868.5895, Product Code 73 CBK)

Predicate Devices:	**Manufacturer**	**Device Name**	**510(k) Number**
	Respironics California, Inc.	V200 Ventilator	K102054

Description of Device Modification

The V200 Ventilator is a microprocessor controlled, electrically powered, mechanical ventilator. The IntelliTrak Software Option will add a new triggering and cycling mechanism based on the equation of motion for the purpose of improving patient-ventilator synchrony. The IntelliTrak software option is activated and is integrated into the V200 in the same way as other currently marketed V200 software options. It can either be installed in the factory or in the field as an upgrade to existing V200 ventilators. The IntelliTrak option is added to the currently commercially released software version and instrument. Downloading this option will add a "button" to the Graphical User Interface (GUI), which is used to turn IntelliTrak on and off.

Intended Use

The V200 Ventilator is a microprocessor-controlled, electrically powered, mechanical ventilator. It is intended for use by qualified medical personnel in providing continuous or intermittent ventilatory support for adult, pediatric, and neonatal patients as prescribed by a physician. The V200 Ventilator is intended for use in either invasive or non-invasive applications.

The IntelliTrak option provides new triggering and cycling functionality that is intended for use only with adult and pediatric patients in invasive applications.

Determination of Substantial Equivalence

The predicate device is the unmodified V200 Ventilator.

- The proposed V200 Ventilator IntelliTrak option is identical to the existing V200 Ventilator with the exception of the addition of the IntelliTrak option.
- The IntelliTrak option incorporates a new option for triggering and cycling a breath. The subsequent breath delivery (inhalation and exhalation) is unchanged by the addition of the IntelliTrak.
- Bench performance testing was performed for the new option and performance was compared between the Respironics V200 with flow triggering set at 3 LPM and cycling set at 25% of peak flow and the Respironics V200 IntelliTrak option.

Conclusion

The V200 Ventilator with IntelliTrak option has the same intended use as the currently marketed predicate ventilator.

The IntelliTrak option incorporates a new option for triggering and cycling a breath. 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. In addition to the software verification and validation activities, performance testing data demonstrates that the IntelliTrak option does not raise any new questions regarding safety and effectiveness.

The technological characteristics of the currently marketed V200 Ventilators with respect to the control mechanism, operating principle, energy type, ergonomics of the patient interface, firmware, environmental specifications, and performance specifications remain unchanged. Changes to the operational software were made to include the IntelliTrak option only.

This submission contains comparative information, including documentation related to the aforementioned activities to conclude that the V200 Ventilator with IntelliTrak option is substantially equivalent to currently marketed devices cleared by the FDA. These changes do not raise any new questions regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Re: K110795
Trade/Device Name: V200 Ventilator with IntelliTrak Option
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: July 30, 2011
Received: August 1, 2011

Dear Mr. Marshall:

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,

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

4 Indications for Use

510(k) Number (if known):

Device Name: V200 Ventilator with IntelliTrak Option

Indications for Use:

The V200 Ventilator is a microprocessor-controlled, electrically powered, mechanical ventilator. It is intended for use by qualified medical personnel in providing continuous or intermittent ventilatory support for adult, pediatric, and neonatal patients as prescribed by a physician. The V200 Ventilator is intended for use in either invasive or non-invasive applications.

The IntelliTrak option provides new triggering and functionality that is intended for use only with adult and pediatric patients in invasive applications.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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