K110083

510(k) Summary

JAN 13 2012

[Refer to 21 CFR 807.92]

Owner:
Respironics California, Inc.
2271 Cosmos Court
Carlsbad, CA 92011

Contact Person:
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Date Prepared: January 10, 2011

Proprietary Name:
Esprit Ventilator with APRV Option
V200 Ventilator with APRV 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.	Esprit Ventilator	K981072
Respironics California, Inc	V200 Ventilator	K102054
CareFusion	Avea Ventilator	K013642

Intended Use of the Device:
The Esprit and V200 Ventilators are microprocessor controlled, electrically powered, mechanical ventilators. They are 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 Esprit and V200 Ventilators are intended for use in either invasive or non-invasive applications.

The Esprit and V200 Ventilators with APRV Mode are intended for use for invasively ventilated adult and pediatric patients as prescribed by a physician

The intended use is the same as that of the predicate devices, except that the APRV Mode is for use on a subset of the patient population the original devices are cleared for (e.g. neonatal patients and non-invasive applications are excluded).

Device Description:
The Esprit and V200 Ventilators are microprocessor controlled, electrically powered, mechanical ventilators. This modification to the currently marketed Esprit Ventilator and V200 Ventilators is the addition of the APRV Mode.

The APRV Mode is an optional software upgrade. It is both a breath type and ventilation mode intended for invasively ventilated adult and pediatric patient populations. APRV enables the ventilator to deliver gas via an endotracheal tube or tracheostomy tube at two levels of pressure (Press High and Press Low), and allows for spontaneous or supported breathing at both levels.

The APRV Mode is activated via a software download through an I-button and is integrated into the Esprit and V200 Ventilators in the same way as other currently released software options. It can either be installed in the factory or in the field as an upgrade to existing Esprit and V200 ventilators. Downloading this option will add a "button" to the Graphical User Interface (GUI), which is used to turn APRV on and off.

Substantial Equivalence:
The Esprit and V200 Ventilators with APRV Mode have the same intended use as the unmodified ventilators and similar design and technological characteristics as the other standard, currently marketed ventilators.

The APRV Mode incorporates a new mode of ventilation and a new breath type similar to the existing CareFusion Avea and unmodified Esprit and V200 Ventilators. 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 and a clinical simulation were conducted and support the assertion that the APRV Mode does not raise any new questions regarding safety and effectiveness.

The technological characteristics of the currently marketed Esprit and 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 to include the APRV Mode only. No changes are being made to any other mode of ventilation. Therefore, all other modes of ventilation are *identical* to those in the currently marketed Esprit and V200 Ventilators.

This submission contains comparative information, including documentation related to the aforementioned activities to conclude that the Esprit and V200 with APRV Mode 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 13 2012

Ms. Mary Funk
Senior Manager, Regulatory Affairs
Respironics California, Incorporated
2271 Cosmo Court
Carlsbad, California 92130

Re: K110083
Trade/Device Name: Esprit Ventilator with Airway Pressure Release Ventilation (APRV) Mode, V200 Ventilator with Airway Pressure Release Ventilation (APRV) Mode
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: January 9, 2012
Received: January 10, 2012

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. 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

Indications for Use

510(k) Number (if known):

Device Name: Esprit Ventilator with Airway Pressure Release Ventilation (APRV) Mode

Indications for Use:

The Esprit 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 Esprit Ventilator is intended for use in either invasive or non-invasive applications and contains the following modes of ventilation:

- Assist/Control (A/C)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Continuous Positive Airway Pressure (CPAP)
- Spontaneous (Spont)
- Spontaneous/Timed (Spont/T)
- Apnea (Backup Mode)

The Esprit Ventilator with Airway Pressure Release Ventilation (APRV) Mode is intended for use only on invasively ventilated adult and pediatric patients as prescribed by a physician.

Prescription Use	X	AND/OR	Over-the-Counter Use	
(Part 21 CFR 801, Subpart D)			(Part 21 CFR 807, Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-...
Division of Anesth... General Hospital
Infection Control, Dental Devices

510(k) Number: K110083

Indications for Use

510(k) Number (if known): K110083

Device Name: V200 Ventilator with Airway Pressure Release Ventilation (APRV) Mode

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 and contains the following modes of ventilation:

- Assist/Control (A/C)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Continuous Positive Airway Pressure (CPAP)
- Spontaneous (Spont)
- Spontaneous/Timed (Spont/T)
- Apnea (Backup Mode)

The V200 Ventilator with Airway Pressure Release Ventilation (APRV) Mode is intended for use only on invasively ventilated adult and pediatric patients as prescribed by a physician.

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, Dental Devices

510(k) Number: k110083