RESPIRONICS®

JAN - 9 2009

510(k) Summary

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Date Prepared: 10 September 2008

Trade name: V60 Ventilator
Common Name (Device Type): Assist Ventilator
Classification Regulation (CFR): 21 CR 868.5895
Class: 2
Product Code: 73 – MNT
Panel: Division of Anesthesiology, General Hospital, Infection Control and Dental Devices (73)

Predicate Device:
Vision Ventilator with Auto-Trak (K982454)
BiPAP Synchrony with AVAPS (K070328)
Esprit Ventilator (K981072)

Indications for Use:

The V60 ventilator is an assist ventilator and is intended to augment patient breathing. It is intended for spontaneously breathing individuals who require mechanical ventilation: patients with spontaneous respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea in a hospital or other institutional settings under the direction of a physician.

The Ventilator is intended to support pediatric patients weighing 20kg (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

The V60™ ventilator is a microprocessor controlled positive pressure ventilatory assist system incorporating a user interface with multifunction keys, real-time graphic displays, and integral patient and system alarms. The ventilator provides noninvasive and invasive ventilatory support for spontaneously breathing adult and pediatric patients.

Substantial Equivalence to Predicate Devices:
The predicate devices are the Respironics BiPAP Vision Ventilatory Support System (K982454), the BiPAP Synchrony with AVAPS ventilator, K070328, for AVAPS breath mode and the Esprit ventilator, K981072, which includes the pediatric population.

- The proposed V60 ventilator is substantially equivalent to the BiPAP Vision Ventilatory Support System and the BiPAP Synchrony with AVAPS ventilator and the Esprit in intended use, technology and performance.
- Bench performance testing was performed comparing the new V60 and the predicate devices, and was found to be substantially equivalent.

List of Similarities:

- Similar intended use – the intended use is similar
    - The Vision Ventilator is intended for use by qualified medical personnel in providing ventilatory support for adult patients as prescribed by a physician. The Esprit is intended for both adult and pediatric patients, with very similar performance parameters. Both Vision and the V60 ventilators are intended for use in either invasive or non-invasive applications.
- Similar patient population – the patient population similar
    - Spontaneously breathing individuals who require mechanical ventilation: patients with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea.
    - The addition of the pediatric population is comparable to K981072, Esprit Ventilatory System.
- Same operating principle – the operating principle is unchanged
    - Both the Vision and the V60 ventilators are microprocessor controlled, electrically powered, mechanical ventilators. There have been no changes to the operating principle of the equipment.
        - The breathing system is under microprocessor control
        - The user interface is under microprocessor control, featuring a touch screen and graphical user interface technology.
        - The integral air source is built into the ventilator, eliminating the requirement for a central compressor and piped, medical grade

wall air and/or an individual stand alone compressor for each ventilator.
        - The ability to provide variable oxygen concentrations (21% to 100% O2) from a medical oxygen gas source, including medical grade gas cylinders with suitable regulators
- Same technology – the technology is unchanged
    - Both the Vision and the V60 ventilators are microprocessor controlled, electrically powered, mechanical ventilators.

List of Differences:

- The V60 includes the pediatric population, similar to the secondary predicate, the Esprit ventilator, K981072
- Breathing modes – there are new breath types or breathing modes included in the V60 which combine the breath delivery modes of the BiPAP Vision and the BiPAP Synchrony.

Conclusion:

Performance testing and human factors testing demonstrate that the device is as safe, as effective and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2009

Ms. Mara Caler
Regulatory Affairs
Respironics California, Incorporated
2271 Cosmos Court
Carlsbad, California 92011

Re: K082660
Trade/Device Name: V60 Ventilator, Model V8000
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNT
Dated: December 11, 2008
Received: December 12, 2008

Dear Ms. Caler:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting 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

Indications for Use:

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Prescription Use ____X____ (Part 21 CFR 801, Subpart D) And/or Over-the-Counter Use_____ (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: K082660