K071212

RESPIRONICS®

JUL 30 2007

510(k) Summary

Submitter: Respironics Inc.
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Date: 30 April 2007

Trade name: Esprit Ventilator Speaking mode Option
Common Name (Device Type): Continuous Ventilator
Classification Regulation (CFR): 21 CR 868.5895
Class: 2
Product Code: 73 – CBK
Panel: Division of Anesthesiology, General Hospital, Infection Control and Dental Devices (73)

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 and pediatric patients as prescribed by a physician. The ESPRIT Ventilator is intended for use in either invasive or non-invasive applications. The Speaking Mode software option allows tracheostomized adult and pediatric patients who meet the assessment criteria to vocalize without the need of a speaking valve.

Substantial Equivalence to Predicate Devices:
Predicate device: Esprit Ventilator, K981072
The proposed Esprit Ventilator is identical to the existing Esprit Ventilator with the exception of the addition of the Speaking Mode option.

List of Similarities:

- Similar intended use – the intended use is unchanged
  - The Esprit Ventilator is intended for use by qualified medical personnel in providing continuous or intermittent ventilatory support for adult and pediatric patients as prescribed by a physician. The ESPRIT Ventilator is intended for use in either invasive or non-invasive applications.

- Similar patient circuit – the patient circuit is unchanged
    - The patient circuit is unchanged.
- Same operating principle – the operating principle is unchanged
    - The ESPRIT ventilatory is a microprocessor controlled, electrically powered, mechanical ventilator. 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 35 to 80 PSIG medical oxygen gas source, including medical grad gas cylinders with suitable regulators
        - The ability to operate on a re-chargeable primary battery for 30 minutes (nominal)
        - The ability to be powered by a secondary DC power source (24 VDC) for up to 3 hours
- Same technology – the technology is unchanged
    - The ESPRIT ventilator is a microprocessor controlled, electrically powered, mechanical ventilator. There have been no changes to the technology or equipment hardware.
- Same manufacturing process – the manufacturing process is unchanged
    - There have been no changes to the manufacturing processes for the equipment.

List of Differences:

- Indications for Use
    - The Speaking mode software option allows tracheostomized adult and pediatric patients who meet the assessment criteria to vocalize without the need of a speaking valve (e.g., the Passy-Muir valve).
- Breathing modes:
    - The breathing modes available during active Speaking Mode include pressure control and volume control in A/C, SIMV and CPAP, Pressure Support and Flow Trak. Speaking Mode option is not available while in the NPPV mode. Neonatal option are not available when in Speaking Mode.

The currently marketed Esprit ventilator and the Esprit ventilator with Speaking Mode option both analyze pressure to trigger and cycle the ventilator. In currently marketed ventilators, an external (closed) Speaking Valve is installed to allow the exhaled gas to flow past the vocal cords. In the Speaking Mode option, the Esprit exhalation valve is closed, so that the exhaled gas is allowed to flow past the vocal cords. The exhaled gas pressure is measured to evaluate if (a) the tracheostomy tube has become disconnected or (b) if the tracheostomy tube has become occluded.

Substantial equivalence was established by performance testing. The Table describing the performance testing follows:

Summary of Validation Testing

Parameter	Purpose	Pass/Fail
Speaking Mode (SM) operability	SM operates with VCV with A/C, SIMV, and CPAP; is not functional with NPPV; operates with Flow-Trak; operates with Pressure Support; operates on both adult and pediatric patient types	Pass
Speaking Mode operability	SM is not available for Neonatal patients; is not active after power cycling; is not available when specific alarms are active	Pass
Speaking mode and I-trigger	I-trigger will automatically adjust to pressure triggering if flow triggering is the current trigger type; that only pressure triggering is allowed while in SM; test the accuracy of pressure triggering	Pass
Speaking Mode graphical user interface	Test the ventilator behavior when SM is not installed; confirm the SM related dialogs; test the ventilator behavior when SM is deactivated; confirm that PEEP is always set to zero when SM is active	Pass
Speaking Mode alarms and settings	Confirm alarm performance, including patient disconnect	Pass
Speaking Mode alarms and settings	Confirm alarm performance, including occlusion alarm	Pass
Apnea alarm	Confirm that if apnea alarm occurs while in SM, exhalation valve opens during exhalation	Pass
Maneuvers not available	Confirm that Respiratory Mechanics and expiratory Hold Maneuvers are not available when SM is active	Pass

Parameter	Purpose	Pass/Fail
Displayed patient data	Confirm that data displays are appropriate	Pass
Trending	Confirm that trending values are trended/not trended when SM is active	Pass
Breath delivery	Confirm that exhalation valve is closed during inhalation and exhalation while in SM	Pass
Communications	Confirm that RS 232 and Vuelink communications are operable	Pass

Conclusion:
This testing demonstrates 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

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

JUL 30 2007

Re: K071212
Trade/Device Name: Esprit Ventilator Speaking Mode Option
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: July 12, 2007
Received: July 16, 2007

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 Office of Compliance at (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

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

510(k) Number (if known): K071212

Device Name: Esprit Ventilator (Speaking Mode Option)

Indications for Use:

The ESPRIT ventilatory 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. The Speaking Mode software option allows tracheostomized adult and pediatric patients who meet the assessment criteria to vocalize without the need of a speaking valve.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(acting)

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

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