K072450
page 1/5

RESPIRONICS®

510(k) Summary

Submitter: Respironics Inc.
Address: 2271 Cosmos Court
Carlsbad, CA 92011
Telephone: 760 918 7458
Fax: 760 918 0169

Contact: Mara Caler
Regulatory Affairs
Telephone: 760 918 7458
Fax: 760 918 0169
Email: mara.caler@respironics.com

DEC 12 2007

Date Prepared: 15 August 2007

Trade name: Esprit Ventilator Auto-Trak Sensitivity 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)

Predicate Device:
Esprit Ventilator (K981072)
Vision Ventilator with Auto-Trak (K982454)
Evita XL Ventilator with "Option Mask Ventilation NIV" (K980642)

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 Auto-Trak option is intended for adult and pediatric patients, and automatically triggers and cycles breathing without the need for user-adjustment of I-trigger (sensitivity) and E-cycle thresholds.

Substantial Equivalence to Predicate Devices:
The predicate device is the Esprit Ventilator Flow Triggering option and the Esprit Ventilator Auto Trak Sensitivity option..

- The proposed Esprit Ventilator Auto-Trak is identical to the existing Esprit Ventilator with the exception of the addition of the Auto-Trak option.
- The Esprit Ventilator Auto-Trak is similar to the Vision Ventilator with Auto-Trak as identified in Table 3, Section 12, page 31 and to the Drage Evita (included because is it is similarly classified device (73-CBK)).
- Bench performance testing was performed for the new option and clinical performance was compared between the Respironics Esprit Flow Triggering option and the Respironics Esprit Auto-Trak 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, pediatric and neonatal 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 ventilatory 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.

- Breathing modes – there are no new breath types or breathing modes required.

List of Differences:

- Indications for Use
    - The Auto-Trak Sensitivity option automatically triggers and cycles breathing without the need for user-adjustment of I-trigger (sensitivity) and E-cycle thresholds.
- Algorithms used to determine triggering and cycling sensitivity thresholds
    - Triggering: Auto-Trak monitors changes in pressure and flow patterns throughout exhalation, applying compensation for circuit leaks and triggering an inspiration.
        - Automatically adjusts I-Trigger and E-cycle in the face of changing leaks
        - Provides leak-compensated ventilation
            - Compensation for leaks up to 60 L/min
    - Reduces auto-triggering and I-time too long alarms/conditions
    - Cycling: Auto-Trak automatically cycles breathing based on the pressure and flow patterns at the end of inspiration and beginning of expiration. The threshold used to cycle each breath changes with the patient's breathing pattern and lung dynamics.
- Improved patient comfort especially in NIV
- Makes it easier to set up the patient (no need to set triggering and cycling criteria)

Table 1: Software testing results:

Software Parameter	Purpose	Pass/Fail
Breath Delivery		
Flow Triggering	To validate the accuracy of the flow triggered breaths during Auto-Trak triggering	Pass
Auto-Trak Triggering – Bias Flow	To validate the accuracy of the bias flow used during Auto-Trak triggering; to check for Auto-Trak triggering when leaks are constant and during changes of pt Leak during Exhalation and Inhalation	Pass
Auto-Trak Triggering – Back up Pressure Trigger	To validate that breaths can also be triggered using the back up pressure trigger when Auto-Trak is active	Pass

Software Parameter	Purpose	Pass/Fail
Auto-Trak Triggering – Mask Off Test	To validate that in CPAP or non-invasive modes, breaths will not auto-cycle if a patient's mask is taken off, then returned to the patient, when Auto-Trak is active	Pass
Auto-Trak Triggering – High Leak Test	To validate that when Auto-Trak is active, and a large leak is suddenly blocked, the ventilator will not truncate more than one breath	Pass
Exhalation Sensitivity with and without Auto-Trak active	To validate the Auto-Trak performance when Auto-Trak is active and not active	Pass
Exhalation Sensitivity decreasing with Auto-Trak active	To validate the Auto-Trak Sensitivity when Exhalation is not detected. When flow is not detected at the exhalation flow sensor at the start of exhalation, Auto-Trak will compensate by decreasing the exhaled flow sensitivity for the next breath	Pass
Exhalation Sensitivity Increasing with Auto-Trak	To validate the Auto-Trak performance when Auto-Trak is active and not active.	Pass

Table 2: Performance Testing Results

Test Parameter	Purpose
Auto-Trak triggering and cycling performance	Auto-Trak performance was evaluated in the clinical trial.
Leak Compensated Bias Flow	To evaluate the accuracy of the bias flow at the ventilator output for 6 leak conditions
High Leak Alarm	To evaluate the new high leak alarm
Patient Leak Display	To evaluate the number of breaths before a new displayed value is stabilized and the accuracy of the displayed value

Clinical Investigation:

The primary efficacy objective of this study was to show equivalence in the proportion of subjects in the Auto-Trak (test) and Flow Triggering (control) treatment groups. The primary safety objective of this study was to evaluate the rate of adverse events during the intervention.

Based on the success criteria (at least equivalent performance and patient preference and no increase in adverse events over the predicate device), Auto-Trak was shown to be substantially equivalent in performance, patient preference and no increase in adverse events.

Conclusion:

Performance testing and clinical data 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

DEC 1 2 2007

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

Re: K072450
Trade/Device Name: Esprit Ventilator Auto-Trak Sensitivity Option
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: November 5, 2007
Received: November 6, 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.

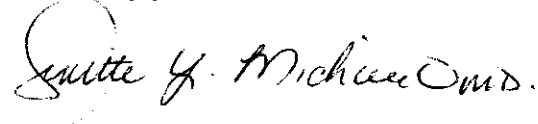
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) K072450

Device Name: Esprit Ventilator Auto-Trak Sensitivity Option

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

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