TAB 3

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Original Date of Submission	19 August 2009
	DEC 18 2009
Device Trade Name	Esprit Ventilator
Common/Usual Name	Ventilator, continuous, life supporting
Establishment Registration #	2518422
Address of Mfr. Facility	Respironics, Inc. 2271Cosmos Court Carlsbad, CA 92011 (724) 387-4120 FAX (724)-387-4216 CELL (724) 882-4120
Classification	Class II device
Classification Panel	Anesthesiology Devices
Classification Reference	21 CFR 868.5895
Product Code	CBK - Continuous ventilator
Predicate Device(s)	Respironics Esprit Ventilator (K072450) Respironics Performax SE Total Face Mask (K072588)
Labeling	Draft Labeling can be found in Tab 5.
Intended 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.
Reason for Submission	Include a Respironics pediatric total face mask to use with this device. Device is unchanged as a result of the addition of this mask

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Substantial Equivalence

The Esprit Ventilator has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

There is no change to the intended use, operating principle, technology or manufacturing process for the Esprit Ventilator. Further, there is no modification required to the electromechanical platform of the Esprit Ventilator as a result of adding this pediatric mask to the existing cleared device (K072450). To demonstrate compatibility of the Respironics Performax Youth SE mask with the Esprit Ventilator, mask compatibility testing was performed. This testing is provided in Tab 8 of this submission. This testing included pressure performance, waveform performance, triggering, cycling and alarm functionality testing. All tests were verified to meet the required acceptance criteria. Results of this testing concluded that the verification testing raises no new issues of safety or effectiveness.

Respironics has followed the FDA's Guidance for Industry and FDA Staff document "pre-market assessment of pediatric medical devices" and applied the principle of FDA's Least Burdensome Approach to demonstrate the Substantial Equivalence of the Esprit Ventilator. As a result we conclude that the existing indications for use can be safely and effectively applied to this device with the new Respironics mask.

Intended 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.

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Device Description

The Respironics Esprit Ventilator is unchanged from K072450. The only change is to include the Respironics Performax Youth SE mask as an option for use by its pediatric users. This mask is the same mask design as is used by the small size of the cleared Respironics Performax SE Total Face Mask (K072588). The mask consists of a silicon cushion, polycarbonate faceplate with an elbow that contains the exhalation feature. The anthropometric profile of the Respironics Performax Youth SE mask was designed to meet the 90^{th} percentile for pediatrics age 7 and older and > 40 lbs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Zita A. Yurko
Director of Regulatory Affairs
Respironics, Incorporated
Sleep & Home Respiratory Group
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

DEC 18 2009

Re: K092648
Trade/Device Name: Esprit Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: November 20, 2009
Received: November 23, 2009

Dear Ms. Yurko:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson, BS, MS, MBA
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

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 noninvasive applications. The Auto-Trak option is intended for adult and pediatric patients, and automatically adjusts I-Triggers and E-Cycles breathing without the need for user adjustment of I-trigger (sensitivity) and E-cycle thresholds under changing leak conditions. The Auto-Trak option provides leak-compensated ventilation for leaks up to 60L/min.

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

L Schlutter

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

510(k) Number: k092648