16 510(k) SUMMARY

Company Information:	Respironics, California Inc. 2271 Cosmos Court Carlsbad, CA. 92009
Contact Information:	Mary Funk Regulatory Affairs Project Manager Phone Number: (760) 918-7328 Fax Number: (760) 918-0169
Date Prepared:	May 12, 2005
Product Name:	Esprit Ventilator Neonatal Option
Common Name:	Ventilator
Classification:	Class II Continuous Ventilator (per 21 CFR 868.5895)
Predicate Devices:	• P-B 840 Ventilator NeoMode Option K001646 • Event Medical Inspiration Ventilator K021112 • Siemens Servo 300 Ventilator K970839 • Dräger Evita 4 Ventilator NeoFlow Option K983219

16.1 Device Description:

The Neonatal Option is a software modification to the currently marketed Esprit Ventilator. Once the software is enabled and the neonatal patient type is selected on the Esprit, it provides the following types of ventilatory support to neonatal patients in invasive applications only:

- Assist/Control, Spontaneous Intermittent Mandatory Ventilation (SIMV) or Continuous Positive Airway Pressure (CPAP) modes of ventilation.
- Pressure-Controlled (PC). Available in A/C and SIMV.
- Pressure Support (PS). Available in SIMV and SPONT.
- Apnea Ventilation

Note: certain features of the currently marketed Esprit are not available to neonatal patient types. Refer to the Neonatal Option instructional information for details.

16.2 Intended Use:

The currently marketed Esprit ventilator is intended for use by qualified medical personnel and provides continuous or intermittent ventilatory support for adult and pediatric patients as prescribed by a physician. It is intended for use in either invasive or non-invasive applications.

With the Neonatal Option, the intended patient population is expanded to include intubated neonatal patients with an ideal body weight range from 0.5 kg to 6.5 kg and an endotracheal tube I.D. range from 2.5 – 4.0 mm.

The Esprit Ventilator is not intended for use as an emergency transport ventilator. It is not intended for use in the presence of flammable anæsthetics. PLVC is a prescription use device that is intended for sale by or on the order of a physician.

16.3 Technological Characteristics:

The addition of the Neonatal Option to the currently marketed Esprit does not result in the use of any new technological characteristics. Breath delivery is controlled by software algorithms that are equivalent to those used on the currently marketed Respironics Esprit ventilator (reference K981072).

16.4 Determination of Substantial Equivalence:

The modes/types of ventilation on the Esprit Ventilator with Neonatal Option are similar to those on other currently marketed continuous ventilators. The modified Esprit has similar performance characteristics, similar intended use and similar patient populations to the predicate devices. The addition of the Neonatal Option does not raise new questions of safety or effectiveness. The labeling and instructional information for the Neonatal Option is similar to that of the predicate devices.

16.5 Summary of Performance Testing:

Software verification and validation testing was performed per FDA's Guidance for the Content of Premarket Submissions for Software contained in Medical Devices (1998). Performance testing was successfully completed demonstrating that all design and system level requirements for the Esprit Ventilator with Neonatal Option have been met.

16.6 Conclusion:

The addition of the Neonatal Option to the Esprit Ventilator does not raise new questions of safety and effectiveness when compared to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2005

Ms. Mary Funk
Regulatory Affairs Project Manager
Respironics California, Incorporated
2271 Cosmos Court
Carlsbad, California 92009

Re: K051262
Trade/Device Name: Esprit Ventilator with Neonatal Option
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: May 12, 2005
Received: May 16, 2005

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.

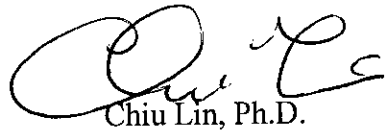
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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

Modification to the Esprit Ventilator
510(k) Premarket Notification for the Neonatal Option

INDICATIONS FOR USE STATEMENT

Applicant: Respironics California, Inc.
2271 Cosmos Court
Carlsbad, CA 92009
USA

510(k) Number: K051262

Device Name: Esprit Ventilator with Neonatal Option

Indications for use: The intended use of the Esprit Ventilator Neonatal Option is to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.

The intended patient population includes intubated neonatal patients with an ideal body weight range from 0.5 kg to 6.5 kg and an endotracheal tube I.D. range from 2.5 – 4.0 mm.

Prescription Use: Yes (Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Owen Faloon K051262

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

510(k) Number: K051262