JUN 1 8 2004

K041412

6 510(k) SUMMARY

Company Information:	Respironics, California Inc. 2271 Cosmos Court Carlsbad, CA. 92009
Contact:	Mary Funk, Regulatory Affairs Project Manager Phone Number: (760) 918-7328 Fax Number: (760) 918-0169
Date Prepared:	May 11, 2004
Product Name:	Esprit Ventilator with the NICO-Esprit Interface
Common Name:	Ventilator
Classification:	Class II Continuous Ventilator (per 21 CFR 868.5895)

Predicate Devices:		
	Respironics Esprit Ventilator	K981072 K001208, K023350, K034040
	Infrasonics Adult Star Ventilator	K964543
	NICO Monitor	K030886

6.1 Device Description:

The NICO-Esprit Interface is a software upgrade to the Esprit Ventilator, which allows the bi-directional communication of the devices to facilitate the transfer of NICO parameters to the Esprit Ventilator as well as the transfer of a patient's breath type information and FiO_2 from the Esprit to the NICO Monitor.

6.2 Intended Use:

The addition of the NICO-Esprit Interface has not changed the original intended use as described in the labeling. 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 to adult and pediatric patients as prescribed by a physician. The Esprit Ventilator is intended for use in either invasive or non-invasive applications.

Esprit is not intended for use in the presence of flammable anæsthetics. Esprit is a prescription use device that is intended for sale by or on the order of a physician.

6.3 Technological Characteristics:

The Esprit ventilator does not incorporate any new technological characteristics with the addition of the NICO-Esprit Interface Option.

6.4 Determination of Substantial Equivalence:

The Esprit Ventilator with NICO-Esprit Interface has similar performance characteristics, the same intended use and the same environment of use and patient populations as the currently marketed predicate devices. The labeling and instructional information, including warning and caution statements, is similar to that of the predicate devices. The addition of this new feature does not raise new questions of safety or effectiveness for the Esprit.

6.5 Summary of Performance Testing:

Safety testing was conducted per the applicable sections of IEC 60601-1-2 and UL 2601. Software validation testing was performed in accordance with FDA's Guidance for the Content of Premarket Submissions for Software contained in Medical Devices (1998). The results of all verification and validation testing demonstrate that all design and system requirements for the Esprit ventilator with NICO-Esprit Interface have been met.

6.6 Conclusion:

The technological characteristics of the Esprit ventilator with NICO-Esprit Interface and the results of the performance testing do not raise new questions of safety and effectiveness and demonstrate that the device is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2004

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

Re: K041412
Trade/Device Name: Esprit Ventilator with NICO-Esprit Interface Option, Model V1000
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: May 26, 2004
Received: May 27, 2004

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 (301) 594-4646. 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/dsma/dsmamain.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

8 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K041412

Device Name: Esprit Ventilator with NICO Esprit Interface

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.

Prescription Use XX
(Per 21 CFR 801 subpart D)

AND/OR

Over-the-counter Use _____
(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: K041412