

K034040  
2 pages

1052

ESPRIT VENTILATOR WITH VCV DEMAND FLOW  
SPECIAL 510(k): Device Modification

JAN 21 2004

8. **510(k) SUMMARY**

**Company:** Respironics California, Inc.

**Address:** 2271 Cosmos Court  
Carlsbad, CA-92009

**Contact:** Anil Bhalani  
Manager, QA/RA

**Date prepared:** December 26, 2003

**Product Common Name:** Continuous Ventilator

**Product Proprietary Name:** Esprit Ventilator  
Model Number: V1000

**Device Classification:** Class II (Special Controls) and 840  
Continuous Ventilator per 21 CFR 868.5895 and  
Diagnostic Spirometer per 21 CFR 868.1  
Procodel: CBK and BZG

**Predicate Devices:** Esprit Ventilator (K023350/K981072)  
Bear 1000 Ventilator (K912619/A)  
Servo Ventilator System (K022132)

**Description of Device Modification:**

The VCV Demand Flow Option is a software option for the currently marketed Esprit Ventilator. It represents an enhancement intended to provide additional flow/volume to patients when operator settings do not satisfy patient demand. VCV Demand Flow is available only in volume controlled mandatory and assist breaths. Once the software is enabled, the VCV Demand Flow feature is always available.

**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 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 anesthetics. Esprit is a prescription use device that is intended for sale by or on the order of a physician.

**Technological Characteristics:**

The Esprit ventilator does not incorporate any new technological characteristics with the addition of the VCV Demand Flow option.

0034

KUBA040

2002

ESPRIT VENTILATOR WITH VCV DEMAND FLOW  
SPECIAL 510(k): Device Modification

**Determination of Substantial Equivalence:**

The Esprit Ventilator with the VCV Demand Flow option has similar performance characteristics, the same intended use, the same environment of use and patient populations as 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 and effectiveness for the Esprit.

**Summary of Performance Testing:**

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 VCV Demand Flow have been met.

**Conclusion:**

The technological characteristics of the Esprit ventilator with the VCV Demand Flow and the results of the performance testing do not raise new questions of safety and effectiveness when compared to the legally marketed predicate devices.



JAN 21 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Anil Bhalani  
Manager of QA/RA  
Respironics, Incorporated  
2271 Cosmos Court  
Carlsbad, CA 92009-1517

Re: K034040  
Trade/Device Name: Esprit Ventilator, Model V1000  
Regulation Number: 868.5895  
Regulation Name: Continuous Ventilator  
Regulatory Class: II  
Product Code: CBK  
Dated: December 26, 2003  
Received: December 29, 2003

Dear Mr. Bhalani:

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.

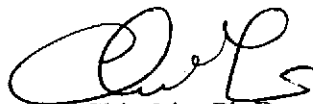
Page 2 – Mr. Bhalani

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

ESPRIT VENTILATOR WITH VCV DEMAND FLOW  
SPECIAL 510(k): Device Modification

**Indications for Use**

510(k) Number (if known): K034040

Device Name: Esprit Ventilator with VCV Demand Flow Option

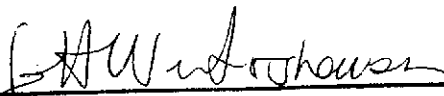
Indications for Use:

*The Esprit Ventilator with VCV Demand Flow Option 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.*

Prescription Use ✓ <sup>MS 4/20/04</sup> OR Over-The -Counter Use \_\_\_\_\_  
(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)

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

510(k) Number: K034040