K981072

NOV 12 1998

2. 510(k) Summary

This 510(k) is being submitted by:
Respironics,
1261 Liberty Way
Vista CA., 92083.
Phone number : 760-727-3500
FAX number: 760-727-8349

The contact personnel for this submittal are:

Paul L. Woodring, primary contact
760-734-3202

Kathy E. Moore, secondary contact
760-734-3221

This summary was prepared on March 23, 1998.

This 510(k) is for the Esprit critical care ventilator, product code (21CFR 868.5895, 73 CBK) The legally marketed predicate devices are the 7200 ventilator offered for sale by Nellcor-Puritan-Bennett; the BIRD Tbird offered for sale by BIRD Medical Products; and the Siemens SV300 offered for sale by Siemens-Elema AB, Electromedical Systems Division. The 7200 ventilator is currently used in both invasive and non-invasive applications. A comparison is also made to the Quantum non-invasive ventilator offered for sale by Healthdyne Technologies (now part of Respironics). Detailed comparisons of the devices can be found in Section 8- Comparative Analysis to Predicate Devices.

The ESPRIT ventilator is a microprocessor controlled, electrically powered, mechanical ventilator. The specific features of the product include:

- Breathing system under microprocessor control.
- User interface under microprocessor control. Uses "human interface" features associated with touch screen and graphical user interface technology. The specifics of the particular touch screen technology and its suitability to medical applications is covered in more detail in the principle of operation section.
- 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 product will also be offered in a configuration without the blower in which case it will operate from a wall air supply.
- Ability to provide variable oxygen concentrations (21% to 100% O_2) from a 35 to 80 PSIG medical grade, oxygen gas source, including medical grade gas cylinders with suitable regulators.
- Ability to operate on a re-chargeable primary battery for 30 minutes (nominal).

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- Ability to be powered by a secondary DC power source (24 VDC) for up to 3 hours.

- Provide high product quality and reliability. ESPRIT has been designed using Highly Accelerated Life Testing (HALT), coupled with Environment Stress Screening (ESS) during manufacturing. Studies have shown that these techniques greatly eliminate reliability problems and are integral to the reliability of the product.

The Esprit Ventilator 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 ESPRIT ventilator is intended to be marketed worldwide as a new ventilator that shall address the needs of low and moderate acuity subacute facilities in the US, surgical recovery units in hospitals, in ICU applications where more expensive options such as trending and waveforms are not required, in stand alone surgery centers in the US and international markets, as well as high acuity intensive care units (ICUs) in undeveloped and emerging nation, rest-of-world (ROW) markets. No medical claims are made regarding the ventilator. It produces the flows and pressures detailed in Section 8 - Comparative Analysis to Predicate Devices. These performance characteristics have been validated with the testing that is summarized in Sections 7 - Table Of Ventilator Requirements, 8 - Comparative Analysis to Predicate Devices and 10 - Environmental Testing.

The determination of equivalence is also based on environmental and lab testing. The ventilator has been tested according to the following environmental standards:

TEST	BASIS
Dielectric Strength	IEC 601-1, Clause 20
Leakage Current	IEC 601-1, Clause 19
Radiated and Conducted Electromagnetic Emissions	CISPR 11
Magnetic Field Emissions	RE101 of MIL-STD 461D at 7 cm
Electrostatic Discharge	IEC 801-2
Radiated Electromagnetic Fields Susceptibility	IEC 801-3
AC Voltage Fluctuation: Steady State, Dropout, Slow Sags and Surges	IEC 801-11
AC Voltage Fluctuation: Fast Transient Bursts	IEC 801-4
AC Voltage Fluctuation: Fast Surges	IEC 801-5
Conducted Electromagnetic Energy Susceptibility	MIL-STD-461D, CS114
Magnetic Fields Susceptibility	RS101(Army) of MIL-STD-461D
Quasi-static Electric Fields Susceptibility	Reviewer Guidance for Premarket Notification Submissions, November, 1993
Random Vibration	Reviewer Guidance for Premarket Notification, Submissions, November, 1993
Shock	Test conditions based on IEC 68-2-27
Ingress of Liquids	IEC 601-1, Clause 44.6, and IEC 529
Temperature/Humidity	Reviewer Guidance for Premarket Notification Submissions, November, 1993.
Surface Temperature	Reviewer Guidance for Premarket Notification Submissions, November, 1993

Table 1 - Environmental Standards

Section 7 - Table Of Ventilator Requirements includes a table demonstrating how the Esprit ventilator meets the requirements called out in the "Draft Reviewer Guidance for Ventilators, July, 1995" Finally, Section 8 - Comparative Analysis to Predicate Devices includes a summary of performance testing comparing the Esprit ventilator to the 7200 predicate device.

A description of waveform performance is covered in 8.3 - Waveform Comparisons to 7200 Ventilator predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Paul L. Woodring
Respironics Inc.
1261 Liberty Way
Vista, Ca. 92083

Re: K981072
Esprit Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: August 14, 1998
Received: August 18, 1998

Dear Mr. Woodring:

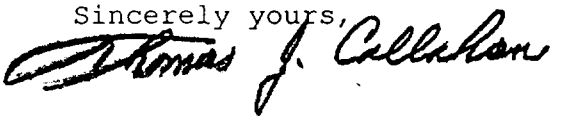
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K981072

Device Name: Esprit Ventilator

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.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981072

prescription use ✓ OTC ____