K093476

TAB 3

JAN 29 2010

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Original Date of Submission	30 October 2009
Device Trade Name	Trilogy 200
Common/Usual Name	Ventilator, continuous, life supporting
Establishment Registration #	2518422
Address of Mfr. Facility	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-4120 FAX (724)-387-7490 CELL (724) 882-4120
Classification	Class II device
Classification Panel	Anesthesiology Devices
Classification Reference	21 CFR 868.5895
Product Code	CBK – Continuous Ventilator, Facility Use
Predicate Device(s)	Respironics Trilogy 100 (K083526)
Labeling	Draft Labeling can be found in Tab 5.
Indications for Use	The Respironics Trilogy200 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy200 is intended for pediatric through adult patients weighing at least 5 kg (11 lbs.). The device is intended to be used in home, institution/hospital, and portable applications such as wheelchairs and gurneys, and may be used for both invasive and non-invasive ventilation.
Reason for Submission	Modified device

Substantial Equivalence

The Trilogy 200 system 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 Trilogy 200. There are minor mechanical changes to the platform of the Trilogy 200 to accommodate the universal porting block modification discussed in this submission. All other modifications did not change the electromechanical platform of the Trilogy 100, cleared in K083526.

To demonstrate performance and functionality of the Trilogy was unaffected as a result of these changes, extensive waveform performance, triggering and alarm functionality testing was performed. 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 Trilogy 200 system. As a result we conclude that the existing indications for use can be safely and effectively applied to this device.

Device Description

The Respironics Trilogy 200 Ventilator Ventilatory Support System is a microprocessor controlled blower based pressure support, pressure control or volume controlled ventilator intended for the care of individuals who require mechanical ventilation. The ventilator is suitable for use in the institutional/hospital, home and transport settings and is applicable for adults and pediatric patients weighing at least 5 kg (11 lbs) who require the following types of ventilatory support.

CPAP – Continuous Positive Airway Pressure

S – Spontaneous Ventilation

S/T – Spontaneous and Timed Ventilation

T – Timed Ventilation

PC – Pressure Control Ventilation

PC-SIMV – Pressure Controlled Synchronized Intermittent Mandatory Ventilation

AC – Assist Control Ventilation

CV – Control Ventilation

SIMV – Synchronized Intermittent Mandatory Ventilation

A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters.

The Trilogy 200 Ventilator is fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable.

The Trilogy 200 Ventilator can deliver therapy to patients > 5kg (11 lbs), invasively (via ET tube) or non-invasively (via masks that are cleared for use with this patient population including small child, pediatric and adult sizes).

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

JAN 29 2010

Re: K093416
Trade/Device Name: Trilogy 200
Regulation Number: 21CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: October 30, 2009
Received: November 2, 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K093416

Device Name: Trilogy 200

The Respironics Trilogy 200 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy200 is intended for pediatric through adult patients weighing at least 5 kg (11 lbs.).

The device is intended to be used in home, institution/hospital, and portable applications such as wheelchairs and gurneys, and may be used for both invasive and non-invasive ventilation.

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)

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

510(k) Number: K093416