TAB 5

K083526

MAR 13 2009

510(K) SUMMARY

Date of Submission	30 November 2008
Official Contact	Zita A. Yurko Director, Regulatory Affairs Respironics, Inc. 1740 Golden Mile Highway Monroeville, PA 15146 Zita.yurko@respironics.com 724-387-4120 t 724-882-4120 c 724-387-7490 f
Classification Reference	21 CFR 868.5895
Product Code	NOU – Continuous Ventilator, Home Use CBK – Continuous Ventilator, Facility Use
Common/Usual Name	Ventilator, continuous, non-life supporting
Proprietary Name	Respironics Trilogy 100 Ventilator Ventilatory Support System
Predicate Device(s)	Respironics BiPAP Synchrony with AVAPS (K070328) Respironics PLV Continuum P2000 (K022750) Pulmonetic LTV-1000 (K984056/K051767) Newport Medical HT-50 (K9912133)
Reason for submission	New Device

Substantial Equivalence

The Trilogy 100 Ventilator has the following similarities to the selected cleared predicate devices:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

The modes of ventilation on Trilogy 100 are similar to those on other currently marketed continuous ventilator. Trilogy 100 has similar performance characteristics to the predicate devices, as listed below, as such; the Trilogy 100 ventilator does not raise any new questions of safety or effectiveness.

The following features are either unchanged or similar to the Respironics BiPAP Synchrony with AVAPS (K070328):

- o Environment of Use
- o Physical Characteristics of the Design
- o Physical Characteristics of the Manufacturing Process
- o Physical Characteristics of the Energy Delivered
- o Physical Characteristics of the Materials
- o Physical Characteristics of the Anatomical Sites
- o Physical Characteristics of the Energy Source
- o Rise Time
- o Ramp
- o Triggering
- o Pressure Regulation method
- o Alarm/Power Control Indicators
- o Patient Alarms (for Pressure Support modalities)
- o System Error Alarms (for Pressure Support Modalities)

- Required Alarms: FDA Reviewers Guidance for Ventilators and ASTM F1100-90 (for MNS class ventilators)
- Device Settings (Tidal Volume)
- Inspiratory Time Setting Method
- Rise Time Setting Method
- Degree of protection against electric shock
- Degree of protection patient applied part
- Pressure Support Modes of Operation (CPAP, S, S/T, T, PC)
- Therapy features (Bi-Flex and AVAPS)

The following features are either unchanged or similar to the Respironics BiPAP PLV Continuum (K034032):

- Patient Population
- Environment of Use
- Product Code
- Physical Characteristics of the Design
- Physical Characteristics of the Manufacturing Process
- Physical Characteristics of the Energy Delivered
- Physical Characteristics of the Materials
- Physical Characteristics of the Anatomical Sites
- Physical Characteristics of the Modem
- Physical Characteristics of the Energy Source
- Rise Time
- Ramp
- Triggering
- Pressure Regulation method

- Alarm/Power Control Indicators
- Patient Alarms for CBK devices
- System Error Alarms for CBK devices
- Required Alarms: FDA Reviewers Guidance for Ventilators and ASTM F1100-90 (for CBK class ventilators)
- Data Storage
- Rise Time Setting Method
- Serial Interface
- Degree of protection against electric shock
- Degree of protection patient applied part
- Modes of Operation (Positive Pressure Ventilation, Assist Control, Volume Controlled, Pressure Controlled and Pressure Support)

The following features are either unchanged or similar to the Pulmonetic LTV-1000 (K984056/K051767):

- Patient Population
- Environment of Use
- Product Code
- Physical Characteristics of the Design
- Physical Characteristics of the Manufacturing Process
- Physical Characteristics of the Energy Delivered
- Physical Characteristics of the Materials
- Physical Characteristics of the Anatomical Sites
- Physical Characteristics of the Modem
- Rise Time
- Ramp

- Triggering
- Pressure Regulation method
- Alarm/Power Control Indicators
- Patient Alarms
- System Error Alarms
- Required Alarms: FDA Reviewers Guidance for Ventilators and ASTM F1100-90 (for CBK class ventilators)
- Humidifier
- Humidifier Interface
- Remote Data Access
- Data Storage
- User Interface
- Real-Time Pressure Display
- Device Settings – display (Pressure)
- Device Settings – display (Rate)
- Device Settings (Tidal Volume)
- Inspiratory Time Setting Method
- Rise Time Setting Method
- Serial Interface
- Degree of protection against electric shock
- Degree of protection patient applied part
- Modes of Operation (Positive Pressure Ventilation, Assist/Control, SIMV, CPAP)

The following features are either unchanged or similar to the Newport Medical HT-50 (K992133):

- Patient Population
- Environment of Use
- Product Code
- Physical Characteristics of the Design
- Physical Characteristics of the Manufacturing Process
- Physical Characteristics of the Energy Delivered
- Physical Characteristics of the Materials
- Physical Characteristics of the Anatomical Sites
- Physical Characteristics of the Modem
- Physical Characteristics of the Energy Source
- CPAP Pressure Range
- IPAP Pressure Range
- EPAP Pressure Range
- Inspiratory Time Range
- Rise Time
- Ramp
- Triggering
- Pressure Regulation method
- Alarm/Power Control Indicators
- Patient Alarms
- System Error Alarms
- Required Alarms: FDA Reviewers Guidance for Ventilators and ASTM F1100-90 (for CBK class ventilators)
- Remote Data Access
- Data Storage

- Real-Time Pressure Display
- Device Settings – display (Pressure)
- Device Settings – display (Rate)
- Device Settings (Tidal Volume)
- Inspiratory Time Setting Method
- Rise Time Setting Method
- Serial Interface
- Oxygen Safety Valve
- Degree of protection against electric shock
- Degree of protection patient applied part
- Modes of Operation (Positive Pressure ventilation and assist/control, SIMV and CPAP)

Bench testing has confirmed that the Trilogy 100 Ventilator performs equivalently to the cited device predicates. Performance testing was conducted per the applicable sections of ASTM F1100-90, F1246-91, ISO 10651-2 and ISO 10651-6. EMC testing was performed per IEC 60601-1-2. Electrical, mechanical and environmental testing was performed in accordance with the FDA Draft Reviewers Guidance for Pre-market Notification Submission (1993). Software validation testing was performed per FDA's Guidance for the Content of Premarket Submissions for Software contained in Medical Devices (2005). The results of all testing demonstrate that all design and system requirements for the Trilogy 100 have been met.

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 100 Ventilator to its predicate devices. We conclude that the existing and cleared predicate device indications for use can be safety and effectively applied to the Trilogy 100 ventilator.

Intended Use

The Respironics Trilogy100 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy100 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. It is not intended to be used as a transport ventilator.

Device Description

The Respironics Trilogy 100 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, 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 100 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 100 Ventilator can deliver invasive (via ET tube) or non-invasively (via a mask)

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2009

Ms. Zita A. Yurko
Respironics, Incorporated
Sleep and Home Respiratory Group
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K083526
Trade/Device Name: Trilogy 100 Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: February 27, 2009
Received: March 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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting 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): _____

Device Name: ___Trilogy 100 Ventilator_____

The Respironics Trilogy100 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy100 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. It is not intended to be used as a transport ventilator.

Prescription Use ___X____ (Part 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: K073526