July 18, 2019

Respironics Inc.
Ms. Colleen Witt
Senior Regulatory Affairs Manager
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K181166
Trade/Device Name: Trilogy Evo Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK, NOU
Dated: July 5, 2019
Received: July 9, 2019

Dear Ms. Witt:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181166

Device Name
Trilogy Evo Ventilator

Indications for Use *(Describe)*
The Trilogy Evo ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO2, FiO2, CO2, and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional, home, and non-emergency transport settings for example wheelchair or personal vehicle. It may be used for both invasive and non-invasive ventilation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 6: 510(k) Summary

Submitter

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Date of Preparation May 1, 2018

Device

Proprietary Name:	Trilogy Evo (K181166)
Common/Usual Name:	Ventilator, Continuous, Facility Use
Device Classification:	21 CFR 868.5895 - Class II
Classification Name/ Product Code:	CBK, Ventilator, Continuous, Facility Use NOU, Continuous, Ventilator, Home Use DQA, Oximeter CCK, Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
Primary Predicate Device:	Trilogy Series of Ventilators with Oximetry (K111610)
Predicate Devices:	Breas Medical, Vivo 60 (K160481) Puritan Bennett 840 (K151252) VOCSN Unified Respiratory System (URS) (K162877) BiPAP A40 Ventilatory Support System (K121623)
Reference Device:	Philips NM3 Monitor, Model 7900 (K091459)

Device Description

The Trilogy Evo ventilator 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 intended to provide continuous or intermittent ventilatory support. The ventilator is suitable for use in institutional, home, and non-emergency transport settings for example wheelchair or personal vehicle. It is applicable for adults and pediatric patients weighing at least 2.5 kg who require the following types of ventilatory support:

Control Modes
- A/C-PC: Assist control
- A/C-VC: Assist control

Spontaneous modes
- CPAP: Continuous positive airway pressure
- PSV: Pressure support ventilation

Mixed modes
- S/T: Spontaneous/timed ventilation
- SIMV-PC: Synchronized intermittent mandatory ventilation (pressure control)
- SIMV-VC: Synchronized intermittent mandatory ventilation (volume control)

AVAPS-AE modes
- AVAPS-AE with PC Breath enabled, with auto backup
- AVAPS-AE with PC Breath enabled, without auto backup
- AVAPS-AE with PC Breath disabled, with auto backup
- AVAPS-AE with PC Breath disabled, without auto backup

The AVAPS-AE mode is intended for noninvasive use in adult and pediatric patients weighing over 10kg with Respiratory Insufficiency or Respiratory Failure.

In addition to the therapy modes, the Trilogy Evo provides the following major functions:
- Therapy Features including Backup Ventilation, Inspiratory Time Min/Max and Sigh
- Power Management of various power sources (AC, internal and detachable Li-Ion batteries and external Pb-Acid battery)
- Physiological alarms
- Graphical User Interface using a touch screen display, status LEDs and dedicated keys for user input
- Bluetooth and USB Communications
- Compatibility with various patient interfaces and multiple circuit types
- Remote alarm and nurse call capability
- Connectivity with hospital monitors
- Capability to connect, display and alarm SpO2, FiO2 and ETCO2 monitors
- Ventilation with supplemental low flow oxygen or oxygen blender

The associated accessories include:
- Filters
- Circuits, including Passive, Active and Dual Limb, and Mouth Piece Ventilation
- FiO2 Sensor
- Active Exhalation Valves
- Leak Device
- Oximeter and Sensors
- Capnography Sensors and cable
- Flow Sensors
- Detachable Battery and Battery Cables

- Nurse Call cables
- Roll Stand
- Mounting Bracket

Indications for Use

The Trilogy Evo ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO2, FiO2, CO2, and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional, home, and non-emergency transport settings for example wheelchair or personal vehicle. It may be used for both invasive and non-invasive ventilation.

The Intended Use of the Trilogy Evo is the same as compared to the primary predicate, Trilogy Series of Ventilator with Oximetry, K111610, to provide invasive and noninvasive positive pressure ventilation. The Indications for Use for the Trilogy Evo is not identical to the predicate device, Trilogy Series of Ventilator with Oximetry, K111610; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.

Comparison of Technological Characteristics with the Predicate Device

The Trilogy Evo ventilator is similar to the Primary Predicate Device, Trilogy Series of Ventilator with Oximetry, K111610. The Trilogy Evo ventilator has the same intended use and similar indications for use, operating principles, technologies and manufacturing processes as the predicate device. See table below for a comparison of the Trilogy Evo ventilator to the primary predicate device, Trilogy Series of Ventilator with Oximetry, K111610.

Comparison of Technological Characteristics with the Predicate Device

Characteristic	Subject Device: Trilogy Evo Manufacturer: Respironics	Predicate Device: Trilogy Series Ventilator with Oximetry (K111610)Manufacturer: Respironics	Comments
Intended Use	The Trilogy Evo ventilator provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo is intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator can measure, display, record, and alarm SpO2, FiO2, CO2, Respiratory Rate, and Pulse Rate data when integrated with the appropriate accessories. The ventilator is suitable for use in institutional, home, and non-emergency transport settings for example wheelchair or personal vehicle. It may be used for both invasive and non-invasive ventilation.	The Trilogy Series of Ventilators (with or without the oximetry interface kit) are intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation with or without air/oxygen blending. Trilogy is intended for pediatric through adult patients weighing at least 5kg (11lbs). The Oximetry Interface kit is intended to measure functional oxygen saturation of arterial hemoglobin (%SPO2) and pulse rate. The device is intended to be used in the home, hospitals and institutions, and portable applications such as wheelchairs and gurneys. It may be used for both invasive and noninvasive ventilation. It is not intended to be used as a transport ventilator.	Substantially equivalent to K111610. Patient weight expanded from 5.0 kg to 2.5 kg. Comparison testing with predicate ventilator demonstrates substantial equivalence. AVAPS-AE Mode is substantially equivalent to the predicate device, BiPAP A40 (K121623). The mode is limited to that intended patient population.
Patient population	Pediatrics and Adults	Pediatrics and Adults	Substantially equivalent
Principle Of Operation	Microprocessor controlled Electronically powered Software driven	Microprocessor controlled Electronically powered Software driven	Substantially equivalent.
Performance	Met ISO 80601-2-12 and 80601-2-72 requirements on essential performance of ventilators	Met ISO 80601-2-12 and 80601-2-72 requirements on essential performance of ventilators	Substantially equivalent
Waveform Comparison	Comparable waveform results	Comparable waveform results	Substantially equivalent

Characteristic	Subject Device: Trilogy Evo Manufacturer: Respironics	Predicate Device: Trilogy Series Ventilator with Oximetry (K111610)Manufacturer: Respironics	Comments
Design	Consists of a graphic user interface with LCD with touch screen	Consists of an LCD screen, hard keys and LED indicators	Substantially equivalent.
Delivery method to patient	Continuous or intermittent positive pressure ventilation	Continuous or intermittent positive pressure ventilation	Substantially equivalent
Energy Used for device	AC and DC (Battery) Power	AC and DC (Battery) Power	Substantially equivalent
Principle of Operation	Microprocessor controlled	Microprocessor controlled	Substantially equivalent
Therapy Types	Invasive and Non-Invasive Mechanical ventilation	Invasive and Non-Invasive Mechanical ventilation	Substantially equivalent

The additional predicate devices, Vivo 60 (K160481), Puritan Bennett 840 Series Ventilator System (K151252) and VOCSN Unified Respiratory System (K162877) were selected as predicate devices to support the following:

- PB 840 supports Trilogy Evo's expanded patient weight of greater than 2.5 kg and expanded settings for several mode parameters.
- Vivo 60 supports Trilogy Evo's CO_2 monitoring, FiO_2 monitoring, the dual limb circuit as well as expanded settings for several mode parameters
- VOCSN URS supports Trilogy Evo's Mouthpiece Ventilation

The reference device, NM3_7900 (K091459) was selected as a reference device to support Trilogy Evo's dynamic lung parameters.

Performance Data

Non-Clinical Tests

Software verification and validation testing
Software verification and validation testing was performed on the Trilogy Evo ventilator based on the product requirements. Testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." This software was considered to have a "major" level of concern, since a failure in the software could result in death or serious injury to the patient.

Verification Testing included the following:

- System Performance
- Closed Loop Control Testing
- Environmental Testing
- Cleaning and Disinfection
- Sterilization, where applicable
- Durability testing
- Power Management
- Alarm performance testing
- User Interface testing
- Therapy mode performance testing
- Connectivity testing
- Comparison Performance Waveform and Triggering / Cycling testing
- DO-160 Testing
- RFID following AIM Standard

All product requirements have been met with passing test results.

Biocompatibility Testing
The biocompatibility evaluation for the Trilogy Evo device was conducted in accordance with FDA Guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA. Biocompatibility testing (i.e. cytotoxicity, sensitization, irritation, genotoxicity and implantation) including extractable and leachables and evaluation/risk assessment as well as condensate testing has been performed.

The materials which are in the gas pathway have been evaluated via Gas emission VOC, Inorganic gases (CO, CO_2, and Ozone) and $PM_{2.5}$ testing with a risk based assessment.

The materials were found to be biocompatible for the intended use, intended population and type of patient contact.

General Safety, Electrical Safety and Electromagnetic Compatibility (EMC)
General Safety, Electrical safety and EMC testing were conducted on the Trilogy Evo device. The system complies with the following standards:

- AAMI/ANSI/ES 60601-1:2005/A1:2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2013
- IEC 60601-1-8:2012
- IEC 60601-1-11:2015
- ISO 80601-2-12:2011

- ISO 80601-2-55:2011
- ISO 80601-2-61: 2011
- ISO 80601-2-72: 2015
- ISO 5356-1:2015
- ISO 5367:2014

Human Factors

The Trilogy Evo ventilator has been found to be appropriate for the intended users, uses, and use environments. The Human Factors/Usability Engineering process followed on this project aligns with IEC 62366-1, Medical Devices – Part 1: Application of Usability Engineering to Medical Devices, and the latest applicable FDA guidance, Applying Human Factors and Usability Engineering to Medical Devices (February, 2016). Results of following this process, in particular the results of the human factors validation study, indicate that intended users can operate the Trilogy Evo ventilator appropriately and that residual risk associated with use of the device is acceptable.

Guidance Documents

The following guidance documents were used in the design and testing of the Trilogy Evo ventilator:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Compliance on Off-The-Shelf Software Use in Medical Devices
- General Principles of Software Validation
- Applying Human Factors and Usability Engineering to Medical Devices
- Design Considerations for Devices Intended for Home Use
- Design Considerations and Pre-Market Submission Recommendations for Interoperable Medical Devices
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- Cybersecurity for Networked Medical Devices Containing Off- the-Shelf (OTS) Software
- Management of Cybersecurity in Medical Devices
- Radio Frequency Wireless Technology in Medical Devices
- Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically Powered Medical Devices
- Pulse Oximeters – Premarket Notification Submissions [510(k)s]

The testing of Trilogy Evo verified that all product requirements have been met with passing test results. The verification and validation testing demonstrated the overall substantial equivalence of the Trilogy Evo device.

Clinical Tests

Clinical tests were not required to demonstrate the safety and effectiveness of the Trilogy Evo ventilator. Product functionality has been adequately assessed by non-clinical tests.

Conclusion

The Trilogy Evo device is as safe and as effective as the predicate device, Trilogy Series Ventilator with Oximetry (K111610) and is deemed substantially equivalent to the predicate device, Trilogy Series Ventilator with Oximetry (K111610).