DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

February 17, 2017

Respironics, Inc.
Elaine Larkin
Senior Regulatory Engineer
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K161411
Trade/Device Name: Care Cycle Connect Application
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MOD
Dated: January 17, 2017
Received: January 19, 2017

Dear Elaine Larkin:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161411

Device Name
Care Cycle Connect

Indications for Use *(Describe)*

The Care Cycle Connect software application is intended for use with Trilogy Series ventilators by both caregivers and clinicians. The application pairs with the Trilogy device via a Bluetooth connection. The application provides the caregiver remote patient monitoring, and alarm surveillance. Alarm surveillance consists of both an audible tone and a visible alert if an alarm condition exists. The application provides the clinician with the ability to view, collect and store patient ventilator usage data. Care Cycle Connect also provides educational information on ventilator use to both caregivers and clinicians.

It's intended to be used in the home, and hospital/ institutional settings. The Care Cycle connect application is intended to supplement and not replace any part of the current device monitoring procedures.

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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TAB 5

510(K) SUMMARY

I. Submitter

Official Contact

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Date of Preparation February 15, 2017

II. Device

Name of Device: Care Cycle Connect

Common/Usual Name: CCC, Medical Device Accessory, Accessory to a Continuous Ventilator

Device Classification: Class II

Classification Name/ Product Code: Accessory to Continuous Ventilator (Respirator) (21 CFR 868.5895, Product Code MOD)

III. Legally Marketed Predicate Devices

- K011861, Bernoulli Ventilator Management System (Cardiopulmonary Corp.)

IV. Device Description

The Care Cycle Connect application is an accessory to a continuous ventilator (product code MOD). Care Cycle Connect is intended for use with the Trilogy Series of

Ventilators cleared by the US FDA under K083526, K093416, K093905, and K111610. Care Cycle Connect (CCC) is a mobile software application designed to provide features and functions related to respiratory care in the home, hospital and institutional - healthcare settings. The application provides the caregiver remote patient monitoring and alarm surveillance.

The CCC application has been designed with two users in mind, the caregiver and the clinician. The functionality of the application is tailored to the different needs of these users and is configured when the application is installed. At the initial start-up of the application, users are asked to choose either caregiver (for patients and their in-home caregivers) or clinician mode. Functionality is based on the configuration selected. Once this choice is made, users cannot switch back and forth between the two configurations.

The primary users expected to interact with Care Cycle Connect in the context of patient care in the home (the main use scenario) are caregivers and respiratory therapists (clinicians). CCC may also be used if the patient is in a hospital or institutional environment (sub-acute care facility). Caregivers are not expected to use CCC in a hospital or institutional setting.

Care Cycle Connect provides constant feedback to the caregiver while the app is connected to the ventilator. This feedback is displayed via the Manometer Display feature within the application. This constant display provides data on the patient's use of the ventilator, ensuring that the ventilator is providing therapy. Care Cycle Connect will also provide educational information on the use of the ventilator to the caregiver or clinician, independent of being connected to the ventilator.

The respiratory therapist will use the app when connected to a patient ventilator while on a home visit to gather ventilator data. It provides an interface for keeping patient information. When the app is not connected to the patient ventilator, the clinician can review stored data, such as appointments, journal, and vent check records. In the

hospital or institutional environment, CCC may be used by clinicians to schedule and perform vent checks, which would be completed in the patient's room.

Care Cycle Connect is an application that can be loaded onto an Apple device (iPad) that uses iOS 8.0 or more recent. The application relies on a Bluetooth Class 1 radio connection to a Trilogy ventilator. With the exception of low level communication protocol information (i.e., handshake connection), the Trilogy device does not accept any data, commands, or controls from the CCC Application. The Trilogy device functionality is not changed in any manner by connecting to the CCC Application. The Trilogy device simply sends information to the CCC Application on a periodic basis.

V. Indications for Use

The Care Cycle Connect software application is intended for use with Trilogy Series ventilators by both caregivers and clinicians. The application pairs with the Trilogy device via a Bluetooth connection. The application provides the caregiver remote patient monitoring, and alarm surveillance. Alarm surveillance consists of both an audible tone and a visible alert if an alarm condition exists. The application provides the clinician with the ability to view, collect and store patient ventilator usage data. Care Cycle Connect also provides educational information on ventilator use to both caregivers and clinicians.

It is intended to be used in the home, and hospital/ institutional settings. The Care Cycle connect application is intended to supplement and not replace any part of the current device monitoring procedures.

While the Indications for Use statement for the Care Cycle Connect Application is not identical to the predicate device, the differences do not alter the intended therapeutic use of the device relative to the predicate. Because the Care Cycle Connect application is intended to be used in the home, in addition to hospital use, testing was completed in accordance with IEC 60601-1-11:2015 Medical Electrical Equipment - Requirements for medical electrical equipment and medical electrical systems used in the home

healthcare environment. Home use of the Care Cycle Connect application has been evaluated through the Risk Assessment process per ISO 14971. Additionally, Usability validation was performed, per IEC 62366.

Both the subject and predicate devices have the same intended use for providing a secondary display of ventilator data and to provide remote monitoring and alarm surveillance. Alarm functionality of the Care Cycle Connect application was designed in accordance with IEC 60601-1- 8:2006 (Second Edition) + Am.1:2012 Medical Electrical Equipment - General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. Both the Care Cycle Connect application and predicate device are intended to supplement and not replace any part of the current device monitoring procedures.

The Care Cycle Connect Application is substantially equivalent when compared to the predicate device.

VI. Comparison of Technological Characteristics with the Predicate Device

Feature/Function	Predicate Device Device Name: Bernoulli Ventilator Management System 510(k) Number: K011861 Manufacturer: Cardiopulmonary Corp.	Subject Device Device Name: Care Cycle Connect 510(k) Number K116411 Manufacturer: Respironics	Comments
Intended Use	The Bernoulli VMS software is intended to be used on a central monitoring station on mechanically ventilated patients in a hospital or hospital type environment. It is used to provide a secondary display of the ventilator data to the central station, and to provide remote monitoring and alarm surveillance. The Bernoulli VMS is intended to supplement and not replace any part of the current device monitoring procedures.	The Care Cycle Connect software application is intended for use with Trilogy Series ventilators by both caregivers and clinicians. The application pairs with the Trilogy device via a Bluetooth connection. The application provides the caregiver remote patient monitoring, and alarm surveillance. Alarm surveillance consists of both an audible tone and a visible alert if an alarm condition exists. The application provides the clinician with the ability to view, collect and store patient ventilator usage data. Care Cycle Connect also provides educational information on ventilator use to both caregivers and clinicians. It is intended to be used in the home, and hospital/ institutional settings. The Care Cycle connect application is intended to supplement and not replace any part of the current device monitoring procedures	Similar – Both applications are intended to provide remote monitoring and alarm surveillance

Feature/Function	Predicate Device Device Name: Bernoulli Ventilator Management System 510(k) Number: K011861 Manufacturer: Cardiopulmonary Corp.	Subject Device Device Name: Care Cycle Connect 510(k) Number K116411 Manufacturer: Respironics	Comments
Environment of Use	Hospital or hospital type environment	Hospital and Home	Hospital use – Substantially equivalent to K011861 Home Use – Care Cycle Connect is intended to be used by Caregivers who are trained and educated to the paired Trilogy Series device
Hardware Install Platform	Application Server (wireless router via Hospital Intranet to Central Monitoring Station, Personal computer, personal digital assistants (PDAs)	Apple iPad; iPad mini (via Bluetooth direct connection)	Similar- Both applications use a mobile platform
User Population	Clinicians	Clinicians and Caregiver	Hospital use – Substantially equivalent to K011861 Home Use – Care Cycle Connect is intended to be used by Caregivers who are trained and educated to the paired Trilogy Series device
Regulatory Classification			
Regulations	868.5895	868.5895	Substantially equivalent to K011861

Feature/Function	**Predicate Device** Device Name: Bernoulli Ventilator Management System 510(k) Number: K011861 Manufacturer: Cardiopulmonary Corp.	**Subject Device** Device Name: Care Cycle Connect 510(k) Number K116411 Manufacturer: Respironics	**Comments**
Product Code	MOD	MOD	Substantially equivalent to K011861
Device Class	2	2	Substantially equivalent to K011861
Prescription Use Only	Yes	Yes	Substantially equivalent to K011861
Viewable Ventilator/Patient Data			
Ventilator Settings	Yes	Yes	Substantially equivalent to K011861
Ventilator/Patient Waveforms	Yes	No for Caregiver Yes for Clinician	Substantially equivalent to K011861
Device Logs	Yes	Yes	Substantially equivalent to K011861
Alarms	Yes	Yes, for Caregiver No for Clinician	Substantially equivalent to K011861
Application Features			
Calendar	No	Yes	Availability of functionality does not impact function of paired Trilogy series ventilator; Optional functionality

Feature/Function	Predicate Device Device Name: Bernoulli Ventilator Management System 510(k) Number: K011861 Manufacturer: Cardiopulmonary Corp.	Subject Device Device Name: Care Cycle Connect 510(k) Number K116411 Manufacturer: Respironics	Comments
Patient Information Record	Yes	Yes	Availability of functionality does not impact function of paired Trilogy series ventilator; Optional functionality
Note Taking (Journal/Daybook)	Unknown; Not identified in 510(K) summary or manufacturer information available via website	Yes	Availability of functionality does not impact function of paired Trilogy series ventilator; Optional functionality
Educational Reference	Unknown; Not identified in 510(K) summary or manufacturer information available via website	Yes (Help Feature)	Availability of functionality does not impact function of paired Trilogy series ventilator; Optional functionality
Software Application Platform	Microsoft Internet Explorer	Apple iOS	Similar – Both applications use software application platforms;
Hardware Install Platform	Application Server (wireless router via Hospital Intranet to Central Monitoring Station, Personal computer, personal digital assistants (PDAs)	Apple iPad; iPad mini (via Bluetooth direct connection)	Similar – Both application use a mobile device

The Care Cycle Connect application has the following similarities to the previously cleared predicate devices:

- Similar intended use
- Similar technological characteristics

Modification #1 – Expanded user population to include caregivers

The Care Cycle Connect application users include caregivers and clinicians. Caregiver use is in addition to the user populations previously cleared in K011861. Caregivers and clinicians have permissions to only view transferred therapy and alarm data. This data is an exact duplicate of the therapy and alarm data that is displayed on the Trilogy Ventilators, which the caregiver is trained to respond to. Neither caregivers nor clinicians have the ability to change device settings through the Care Cycle Connect application. Both caregiver and clinician uses have been evaluated through Risk Assessment process per ISO 14971and Usability per IEC 62366. Based on this assessment, the Care Cycle Connect application has no features or functions defined as essential performance, i.e. there are no features or functions that, if absent or degraded, would render the Trilogy device as unsuitable for its intended use.

Modification #2 – Expanded environment of use to include the home environment

The Care Cycle Connect Application can be used in both the home and the hospital or institutional settings. Institutional settings were cleared in K011861 (Bernoulli Ventilator Management System) and K083526, K093416, K093905, and K111610 (Trilogy Ventilatory Devices). Trilogy Ventilatory devices are cleared by US FDA under K083526, K093416, K093905, and K111610 for home and hospital use. The Care Cycle Connect application is only available for use with a Trilogy ventilator. The home and hospital use environment is considered the same as the Trilogy ventilators. Home use of the Care Cycle Connect application is in addition to the locations of use previously cleared in K011861. Users in the home (caregivers) and clinicians have

permission to only view transferred therapy and alarm data (includes prescription information). Neither Caregivers nor Clinicians have the ability to change device settings through Care Cycle Connect. Home use of the Care Cycle Connect application has been evaluated through Risk Assessment process per ISO 14971 and Usability, per IEC 62366.

Modification #3 - Hardware Install Platform

The substantial equivalence section includes all similarities and differences between the Care Cycle Connect Application and the Bernoulli Ventilator Management System.

The indications for use in K011861, state that the Bernoulli software system is used to provide a secondary display of the ventilator data to the central station, and to provide remote monitoring and alarm surveillance. Bernoulli software allows data to be displayed on mobile devices. Optional mobile devices, such as personal digital assistants (PDAs) and laptops, are supported by the Bernoulli software. The mobile device is configured to receive data from a wireless local area network (WLAN) in the hospital setting. The Care Cycle Connect software is installed on a mobile device (IPad) and communicates with only one Trilogy device at time. This communication is enabled via the Bluetooth technology. The Care Cycle Connect application does not pose any increase in risk in comparison to the predicate devices. Cybersecurity was also assessed as part of risk management. In accordance to the newly finalized FDA guidance, “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” issued on October 2, 2014, a Cybersecurity Hazard Analysis (Security Risk Assessment) was performed. The result of the assessment was that all risks identified have been controlled to acceptable levels.

The Bernoulli Ventilator Management System is used on a central monitoring station but it can also be used on a personal digital assistant (PDA). Bernoulli's distributed alarm system can be routed to a clinician's PDA for vent alarming capability, similar to that of the Care Cycle Connect Application. The transfer of alarms from the Trilogy to an iPad are considered similar applications. These technological differences do not introduce any new risks. Furthermore, the Care Cycle Connect application is an accessory to the Trilogy ventilator and doesn't alter or manipulate the data in any way. With both the Care Cycle Connect Application as well as the Bernoulli Ventilator Management System, the clinician or caregiver must report back to the ventilator to address the alarm. This further substantiates that the applications' use of an IPAD is substantially equivalent to the predicate use of a PDA.

VII. Performance Data:

Software Verification and Validation Testing

Software verification and validation 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 "moderate" level of concern, since a failure or latent flaw in the software could result in minor harm to the patient.

Non-Clinical Tests

Software verification and validation testing was performed on Care Cycle Connect based on the product requirements. This testing included complete system level testing to verify device pairing and connectivity, clinician and caregiver login, clinician patient information, clinician journal entries, clinician vent check records, caregiver appointment and journal entries, help assistant information and Legibility of Alarm and Information Signals. Additionally, usability testing was completed on Care Cycle Connect application.

The Verification and Validation tests comply with the following standards:

- IEC 62304:2006 Medical Device Software – Software Life Cycle Processes
- IEC 60601-1-6:2010 (Third Edition) + A1:2013 Medical Electrical Equipment - General requirements for basic safety and essential performance – Usability
- IEC 60601-1- 8:2006 (Second Edition) + Am.1:2012 Medical Electrical Equipment - General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-11:2015 Medical Electrical Equipment - Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62366: 2007 (First Edition) + A1: 2014 Medical Devices – Application of Usability Engineering to Medical Devices

The following guidance documents were used in the design and testing of Care Cycle Connect, where applicable:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Medical Devices (February 3. 2016)
- FDA Mobile Medical Applications Guidance (September 25, 2013)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2014)
- Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff (August 2013)
- FDA Guidance Design Considerations for Devices Intended for Home Use (November 24, 2014)

The testing of Care Cycle Connect verified that all product requirements have been met with passing test results. The verification and validation testing demonstrated the substantial equivalence of Care Cycle Connect to the predicates.

Clinical Tests

Clinical tests were not required to demonstrate the substantial equivalence of Care Cycle Connect. Product functionality has been adequately assessed by non-clinical tests.

VIII. Conclusion

Care Cycle Connect has passed all of the aforementioned non-clinical tests and required no clinical tests in order to demonstrate substantial equivalence to the predicate device. The Care Cycle Connect application does not raise different questions of safety and effectiveness concerns when used as an accessory to the Trilogy family of ventilators. It is therefore concluded that Care Cycle Connect is substantially equivalent to the predicate device Bernoulli Ventilator Management System, Cardiopulmonary Corp. (K011861).