October 18, 2019

Respironics Inc.
Jennifer Richardson
Regulatory Affairs
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15642

Re: K183226
Trade/Device Name: Care Orchestrator Essence
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD, MNS, MNT, CBK, NOU
Dated: September 17, 2019
Received: September 18, 2019

Dear Jennifer Richardson:

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, Ph.D.
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)*
K183226

Device Name
Care Orchestrator Essence

Indications for Use *(Describe)*
Care Orchestrator Essence is intended for use by healthcare professionals (e.g., Physicians, Clinicians, Durable Medical Equipment providers) to gather, store, manage, and view compliance data for patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. The software also includes the ability to create new or updated prescriptions and/or performance settings, store them, and transmit them to compatible Respironics' non-life supporting therapy devices and Respironics Trilogy ventilator. Data and prescription settings are transferred between Care Orchestrator Essence and compatible devices via removable media. Care Orchestrator Essence is intended to be used in hospital, institutional, provider, and home care settings by healthcare representatives.

The software does not perform automatic scoring or diagnosis. The data it provides are only one of several elements to consider when making decisions about patient therapy.

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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ATTACHMENT B

510(K) SUMMARY

I. Submitter

Official Contact

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Regulatory Affairs Project Manager
amy.panzik@philips.com
Respironics Inc.
1740 Golden Mile Highway
Monroeville, PA 15146

Phone: (412) 542-3644

Date of Preparation September 17, 2019

II. Device

Name of Device: Care Orchestrator Essence

Common/Usual Name: Data Management System

Device Classification: Class II

Classification Name/ Product Code: Noncontinuous ventilator (21 CFR 868.5905, Product Code BZD)

Continuous ventilator (21 CFR 868.5895, Product Codes MNS, MNT, CBK, NOU)

III. Legally Marketed Predicate Device

Predicate: K152356 Sapphire, Respironics Inc.

Trade Name: Care Orchestrator

Reference: K083526 Trilogy/DirectView, Respironics Inc.

Trade Name: Trilogy 100 Ventilator (DirectView)

IV. Device Description

Care Orchestrator Essence software is a desktop solution that allows healthcare representatives (e.g., physicians, clinicians, durable medical equipment providers) involved in a patient's therapy lifecycle the ability to manage patients and referrals; control access to patient information; view and interact with therapy and prescription data from Respironics devices; enhance the patient compliance management workflow; and gain efficiencies in the overall patient therapy workflow.

Care Orchestrator Essence supports patient data management and prescription updates for sleep therapy devices (BZD, MNS, MNT) and Trilogy respiratory devices (CBK, NOU) through an SD card.

V. Indications for Use

Care Orchestrator Essence is intended for use by healthcare professionals (e.g., Physicians, Clinicians, Durable Medical Equipment providers) to gather, store, manage, and view compliance data for patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. The software also includes the ability to create new or updated prescriptions and/or performance settings, store them, and transmit them to compatible Respironics' non-life supporting therapy devices and Respironics Trilogy ventilator. Data and prescription settings are transferred between Care Orchestrator Essence and compatible devices via removable media. Care Orchestrator Essence is intended to be used in hospital, institutional, provider, and home care settings by healthcare representatives.

The software does not perform automatic scoring or diagnosis. The data it provides are only one of several elements to consider when making decisions about patient therapy.

VI. Comparison of Technological Characteristics with the Predicate Device

Care Orchestrator Essence has the following similarities to the legally marketed predicate device:

Predicate: Care Orchestrator	**Reference: DirectView Software**
Similar indications for use	Similar indications for use
Same environment of use	Same environment of use
Similar functionality	Same functionality
Same report capabilities	Same report capabilities

Table 10-1: Comparison of Care Orchestrator Essence to Care Orchestrator (K152356)				
Feature/Function	**Predicate Device:** Device Name: Care Orchestrator (Project Name: Sapphire) 510(k) Number: K152356 Manufacturer: Respironics Inc.	**Reference Device:** Device Name: DirectView 510(k) Number(s): K083526 (also subsequent 510(k) K093416, K093905 and K111610) Manufacturer: Respironics Inc.	**Subject Device:** Device Name: Care Orchestrator Essence (Project Name: Tonic) 510(k) Number: K183226 Manufacturer: Respironics Inc.	**Similarity to Predicate**
Indications for Use	Sapphire is intended to support clinicians by tracking data on patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. Sapphire provides remote patient data collection & viewing and is intended to be used by healthcare representatives (e.g., Physicians, Clinicians, Durable Medical Equipment providers) in conjunction with compatible non-life support	DirectView is a data assessment tool for use by physicians, clinicians, and home care providers to receive and report stored data from an SD data card and select Philips Respironics devices. DirectView can be used to manage a patient's prescription. It provides the trained clinical professional with the ability to transfer new or updated prescriptions to the device via an SD card, but does not allow the	Care Orchestrator Essence is intended for use by healthcare professionals (e.g., Physicians, Clinicians, Durable Medical Equipment providers) to gather, store, manage, and view compliance data for patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. The software also includes the ability to create new or	Similar to predicate devices, K083526 & K152356. Different from K152356 in that Care Orchestrator Essence adds adjustment to prescriptions and/or performance settings via removable media for

Table 10-1: Comparison of Care Orchestrator Essence to Care Orchestrator (K152356)				
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	therapy devices to adjust prescription and/or performance settings. Sapphire allows read-only access to patients. Sapphire is intended to be used in hospital, institutional, provider, and home care settings.	clinician to remotely change a prescription. DirectView does not perform any automatic scoring or diagnosing of a patient's therapy data.	updated prescriptions and/or performance settings, store them, and transmit them to compatible Respironics' non-life supporting therapy devices and Respironics Trilogy ventilator. Data and prescription settings are transferred between Care Orchestrator Essence and compatible devices via removable media. Care Orchestrator Essence is intended to be used in	Trilogy (NOU, CBK) therapy devices. Different from K152356 in that Care Orchestrator Essence does not provide read-only access to patients. Different from K083526 in that Care Orchestrator Essence's indication for

Table 10-1: Comparison of Care Orchestrator Essence to Care Orchestrator (K152356)				
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			hospital, institutional, provider, and home care settings by healthcare representatives. The software does not perform automatic scoring or diagnosis. The data it provides are only one of several elements to consider when making decisions about patient therapy.	use statement specifically identifies prescription and/or performance settings update via removable media for Trilogy life-support therapy devices. The K083526 predicate had this same functionality but did not specifically identify Trilogy in the indication.

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Product Code	BZD, MNS, MNT, NOU, CBK	MNS, MNT, CBK, NOU	BZD, MNS, MNT, NOU, CBK	Equivalent to K083526 and K152356. Care Orchestrator Essence supports prescription and/or performance settings update via removable media for CBK/NOU Trilogy life-support therapy devices only. It is not intended for use with any other life-supporting devices.

Table 10-1: Comparison of Care Orchestrator Essence to Care Orchestrator (K152356)				
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Environment of Use	Care Orchestrator is intended to be used in hospital, institutional, provider and home care settings	DirectView is intended to be used in hospital, institutional, provider and home care settings	Care Orchestrator Essence is intended to be used in hospital, institutional, provider and home care settings	Equivalent to K152356 & K083526.
User Population	Healthcare representatives (e.g., Physicians, Clinicians, Durable Medical Equipment providers) and patients	Healthcare representatives (e.g., Physicians, Clinicians, Durable Medical Equipment providers)	Healthcare representatives (e.g., Physicians, Clinicians, Durable Medical Equipment providers)	Similar to K152356. Care Orchestrator Essence does not provide read-only access to patients. Equivalent to K083526

Table 10-1: Comparison of Care Orchestrator Essence to Care Orchestrator (K152356)				
Feature/Function	**Predicate Device:** Device Name: Care Orchestrator (Project Name: Sapphire) 510(k) Number: K152356 Manufacturer: Respironics Inc.	**Reference Device:** Device Name: DirectView 510(k) Number(s): K083526 (also subsequent 510(k) K093416, K093905 and K111610) Manufacturer: Respironics Inc.	**Subject Device:** Device Name: Care Orchestrator Essence (Project Name: Tonic) 510(k) Number: K183226 Manufacturer: Respironics Inc.	**Similarity to Predicate**
Application Type	Web-based application	Desktop application	Desktop application	Different from K152356. Care Orchestrator requires internet access; Care Orchestrator Essence requires a PC running Windows 7 Service Pack 1 or newer. Equivalent to K083526 Care Orchestrator Essence does not require the internet

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Data transfer technology from therapy device	• Wireless (Bluetooth or cellular modem) • SD Card	• SD Card	• SD Card	Similar to K152356 with regard to data transfer with an SD card. Equivalent to K083526
Data storage	Data is stored on a centralized database	Data is stored on a single PC	Data is stored on a single PC	Different from K152356 Equivalent to K083526
Functionality	• Patient management • Display therapy data • Generate reports • Prescription Settings management for non-life supporting devices (BZD, MNS, MNT)	• Patient management • Display therapy data • Generate reports • Settings management for non-life supporting and life supporting devices	• Patient management • Display therapy data • Generate reports • Prescription Settings management for non-life supporting devices	Similar to K152356 Care Orchestrator Essence has additional functionality for Prescription Settings

Table 10-1: Comparison of Care Orchestrator Essence to Care Orchestrator (K152356)				
Feature/Function	**Predicate Device:** Device Name: Care Orchestrator (Project Name: Sapphire) 510(k) Number: K152356 Manufacturer: Respironics Inc.	**Reference Device:** Device Name: DirectView 510(k) Number(s): K083526 (also subsequent 510(k) K093416, K093905 and K111610) Manufacturer: Respironics Inc.	**Subject Device:** Device Name: Care Orchestrator Essence (Project Name: Tonic) 510(k) Number: K183226 Manufacturer: Respironics Inc.	**Similarity to Predicate**
			and Trilogy life supporting device	management for Trilogy (NOU/CBK) devices. Equivalent to K083526
Settings management	Ability to change device settings wirelessly or via a Secure Digital (SD) card in non-life support devices only.	Ability to change device settings in all supported Respironics devices via a Secure Digital (SD) card. No wireless access.	Ability to change device settings in all supported Respironics devices via a Secure Digital (SD) card. No wireless access.	Similar to K152356. Equivalent to K083526
Reports	Detailed Report (includes compliance information)	Detailed Report (includes compliance information)	Detailed Report (includes compliance information)	Equivalent to K152356 & K083526.

Table 10-1: Comparison of Care Orchestrator Essence to Care Orchestrator (K152356)				
Feature/Function	**Predicate Device:** Device Name: Care Orchestrator (Project Name: Sapphire) 510(k) Number: K152356 Manufacturer: Respironics Inc.	**Reference Device:** Device Name: DirectView 510(k) Number(s): K083526 (also subsequent 510(k) K093416, K093905 and K111610) Manufacturer: Respironics Inc.	**Subject Device:** Device Name: Care Orchestrator Essence (Project Name: Tonic) 510(k) Number: K183226 Manufacturer: Respironics Inc.	**Similarity to Predicate**
Labeling	Online help file within the application	Online help file within the application	Online help file within the application	Equivalent to K152356 & K083526.
Viewing of data	Rendered, static PDF based on user selected date range.	Interactive viewing of data based on user selected date range.	Interactive viewing of data based on user selected date range.	Different from K152356. Equivalent to K083526

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."

Non-Clinical Tests

Software verification and validation testing was performed on Care Orchestrator Essence based on the product requirements. This testing included complete system testing to verify data transfer through an SD card from therapy devices to Care Orchestrator Essence. Once data was transferred, all tests confirmed that Care Orchestrator Essence can display patient and device information, display therapy data including summary and therapy reports and allow for a user to create and/or edit a patient's prescription for the supported therapy devices. Verification of cybersecurity requirements implemented within the software and system architecture were also confirmed for user authentication and encryption of data at rest. Labeling controls as identified in the risk and cybersecurity risk analysis were also verified. Unit verification and low level tests of prescription integrity checks were also completed.

The testing of Care Orchestrator Essence verified that all product requirements have been met with acceptable test results. The verification and validation testing demonstrated comparable safety and effectiveness of the Care Orchestrator Essence software in comparison to the predicate software, Care Orchestrator and DirectView.

Clinical Tests

Clinical tests were not required to demonstrate the safety and effectiveness of Care Orchestrator Essence. Product functionality has been adequately assessed by non-clinical tests.

VIII. Conclusion

Care Orchestrator Essence has demonstrated acceptable test results for all of the aforementioned non-clinical tests and required no clinical tests in order to demonstrate safety or effectiveness. It is therefore concluded that Care Orchestrator Essence is substantially equivalent to the predicate devices, Care Orchestrator (K152356) and DirectView (K083526).