January 4, 2019

Respironics Inc.
Ankitha Rao
Regulatory Project Manager
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K181053
Trade/Device Name: Care Orchestrator
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD, MNS, MNT, CBK, NOU, CAW
Dated: December 5, 2018
Received: December 6, 2018

Dear Ankitha Rao:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181053

Device Name
Care Orchestrator

Indications for Use *(Describe)*
Care Orchestrator 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. Care Orchestrator 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 therapy devices to adjust prescription and/or performance settings. Care Orchestrator allows read-only access to patients. Care Orchestrator is intended to be used in hospital, institutional, provider, and home care settings.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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TAB 5
510(K) SUMMARY

I. Submitter

Official Contact

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Date of Preparation April 18, 2018

II. Device

Name of Device: Care Orchestrator

Common/Usual Name: Data Management System

Device Classification: Class II

Classification Name/ Product Code:

Non-continuous ventilator (21 CFR 868.5905, Product Code BZD)

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

Portable oxygen generator (21CFR868.5440, Product Code CAW)

III. Legally Marketed Predicate Device

K152356 Sapphire, Respironics Inc.
Trade Name: Care Orchestrator

IV. Device Description

Care Orchestrator is a solution that will provide entities involved in a patient's therapy lifecycle with the ability to manage patients and referrals, control access to patient information and therapy data, interact with billing information, enhance patient compliance management workflow, manage the resupply of medical equipment, and gain efficiencies in the overall Patient Therapy Workflow.

Care Orchestrator will support patient data management for sleep therapy devices (BZD, MNS, MNT) and respiratory devices (CBK, NOU, CAW). Care Orchestrator will support prescription updates for sleep therapy devices. There are no input flows to the respiratory device interfaces (Bluetooth and SD Card). Device prescription and settings are read-only for these respiratory device types.

V. Indications for Use

Care Orchestrator 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. Care Orchestrator 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 therapy devices to adjust prescription and/or performance settings. Care Orchestrator allows read-only access to patients. Care Orchestrator is intended to be used in hospital, institutional, provider, and home care settings.

VI. Comparison of Technological Characteristics with the Predicate Device

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

- Similar intended use
- Same operating principle
- Same technology
- Same manufacturing (deployment) process

Feature/Function	**Predicate Device** Device Name: Care Orchestrator (Project: Sapphire) 510(k) Number: K152356 Manufacturer: Respironics Inc.	**Subject Device** Device Name: Care Orchestrator (modified) 510(k) Number: TBD Manufacturer: Respironics Inc.	**Comments**
Indications for Use	Sapphire is intended to support clinicians by tracking data on patients who are prescribed compatible therapy devices in	Care Orchestrator is intended to support clinicians by tracking data on patients who are prescribed	Equivalent to K152356.

	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 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.	compatible therapy devices in accordance with the intended use of those therapy devices. Care Orchestrator 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 therapy devices to adjust prescription and/or performance settings. Care Orchestrator allows read-only access to patients. Care Orchestrator is intended to be used in hospital, institutional, provider, and home care settings.	Remote setting change functionality is not applicable to Respironics CBK, NOU and CAW therapy devices.
Application	Web based application	Web based application	Equivalent to K152356.
Data storage	Data stored on centralized database	Data stored on centralized database	Equivalent to K152356.
Functionality	• Patient management • Display therapy data • Generate reports • Settings management for non-life supporting devices	• Patient management • Display therapy data • Generate reports • Settings management for non-life supporting devices	Equivalent to K152356. Remote setting change functionality is not applicable to Respironics CBK, NOU and CAW therapy devices or any Respironics devices that are intended for life-support.
Settings management	Ability to remotely change device settings in non-life support devices only.	Ability to remotely change device settings in non-life support devices only.	Equivalent to K152356.
Reports	Detailed Report (includes compliance information)	Detailed Report (includes compliance information)	Equivalent to K152356.

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 Orchestrator based on the product requirements. This testing included complete system testing to verify data transfer from therapy devices to Care Orchestrator, through both wireless data transfer and SD card data transfer. Once data was transferred, all tests confirmed that Care Orchestrator can display patient and device information, display therapy data including compliance and therapy reports and allow for a user to create and/or edit a patients prescription for an applicable therapy device.

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

Clinical Tests

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

Summary of additional feature(s) from the Care Orchestrator (K152356)

- Portable oxygen generator (Product Code CAW) Support
- Support of additional therapy device models (Product codes BZD, MNT, MNS, CBK/NOU)
- Therapy data download via removable media (SD card) for Product codes CBK/NOU
- Task Management
- Configurable compliance and health rules
- Enhancements to user and organization management capability including external authorizations
- Enhancements to reporting capability including custom report templates
- Patient management enhancements including search capability, activity log, notes, and document attachments
- Display of device health information
- Product support console
- Legacy application data migration and synchronization

The inclusion of these features has been assessed within the risk analysis and no additional safety risks have been found as a result of the inclusion of these features.

VIII. Conclusion

The modified Care Orchestrator is as safe and as effective as the predicate device, Care Orchestrator (K152356) and is deemed substantially equivalent to the predicate device, Care Orchestrator (K152356).