September 25, 2020

Respironics, Inc.
Jennifer Richardson
Senior Regulatory Affairs Engineer
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K201439
Trade/Device Name: Care Orchestrator with Home Sleep Testing
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: August 21, 2020
Received: August 24, 2020

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,

for Malvina B. Eydelman, M.D.
Director
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)*
K201439

Device Name
Care Orchestrator with Home Sleep Testing

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. In addition, Care Orchestrator can be used for analysis (automatic and manual scoring), display, retrieval, summarization, and report generation of data received from compatible monitoring devices used to categorize sleep-related events that help aid in the diagnosis of sleep-related disorders. The Home Sleep Testing function of Care Orchestrator is indicated for Adult use only. 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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5
510(K) SUMMARY

I. Submitter

Official Contact Jennifer Richardson

Senior Regulatory Affairs Engineer
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Monroeville, PA 15146
Phone: 812-322-1116

Manufacturing Facility Respironics Inc.

1001 Murry Ridge Ln
Murrysville, Pennsylvania 15668

Date of Preparation 25 September 2020

II. Device

Name of Device: Care Orchestrator with Home Sleep Testing
Common/Usual Name: Data collection and patient management software
Regulatory Class: II

Regulation	Product Code	Classification Name	Status
21 CFR §868.5905	BZD	Ventilator, Non-Continuous (Respirator)	Primary Product Code
21 CFR §868.5895	MNS	Ventilator, Continuous, Non-life-supporting	Subsequent Product Code
	MNT	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	Subsequent Product Code
	NOU	Continuous Ventilator, Home Use	Subsequent Product Code
	CBK	Ventilator, Continuous, Facility Use	Subsequent Product Code
21 CFR §868.5440	CAW	Generator, Oxygen, Portable	Subsequent Product Code
21 CFR §868.2375	MNR	Ventilatory Effort Recorder	Subsequent Product Code

III. Legally Marketed Predicate Device

- Primary predicate: K181053, Care Orchestrator, Respironics Inc.

The predicate has not been subject to any design-related recalls.

- Reference device: Sleepware G3 with Somnolyzer Inside, K142988.

IV. Device Description

Care Orchestrator is a cloud-based software platform that allows entities including physicians, other professional home and clinical staff, and durable medical equipment providers involved in a patient's therapy lifecycle the ability to manage patients and referrals, control access to patient information and therapy data, enhance patient compliance management workflow, and gain efficiencies in the overall patient therapy workflow. Care Orchestrator also provides a method for sleep data acquired from a supported home sleep test (HST) devices to be imported, scored and reviewed by a qualified user. The HST function of Care Orchestrator is for adult use only.

The intent of the Care Orchestrator sleep diagnostic functionality is to provide a capability that allows users to analyze, score, review and generate clinical reports for HST acquisitions (i.e. sleep studies) from within a web browser. Users can upload acquisitions to Care Orchestrator and perform these actions all from within the browser-based Care Orchestrator Client application.

Care Orchestrator software has undergone no significant changes since clearance in K181053. The addition of the Home Sleep Testing features, subject of this submission, add a sub-set of Home Sleep Testing functionality.

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. In addition, Care Orchestrator can be used for analysis (automatic and manual scoring), display, retrieval, summarization, and report generation of data received from compatible monitoring devices used to categorize sleep-related events that help aid in the diagnosis of sleep-related disorders. The Home Sleep Testing function of Care Orchestrator is indicated for Adult use only. 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

Feature/Function	**Predicate Device: Care Orchestrator K181053**	**Reference Device: Sleepware G3 with Somnolyzer Inside, K142988**	**Subject Device: Care Orchestrator with Home Sleep Testing (Care Orchestrator with HST)**	**Similarity to Predicate**
Device Type	Stand-alone software	Stand-alone software	Stand-alone software	Unchanged from predicate
Classification	21 CFR §868.5905 21 CFR §868.5895 21 CFR §868.5440	21 CFR §882.1400 21 CFR §868.2375	21 CFR §868.5905 21 CFR §868.5895 21 CFR §868.5440 21 CFR §868.2375	The classification is updated from the predicate to reflect the additional diagnostic functionality.
Product Code	BZD, MNS, MNT, NOU, CBK, CAW	OLZ, MNR, OLV	BZD, MNS, MNT, NOU, CBK, CAW, MNR	Product codes are updated to match new functionality
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	Sleepware G3 is a software application used for analysis (automatic and manual scoring), display, retrieval, summarization, report generation and networking of data received from monitoring devices used to categorize sleep related events that help aid in the diagnosis of sleep related disorders. It is indicated for use with infant or adult patients in a clinical environment by or on the order of a physician. The optional Somnolyzer Inside scoring package has the same intended use as Sleepware G3, but is	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. In addition, Care Orchestrator can be used for analysis (automatic and manual scoring), display, retrieval, summarization, and report generation of data	Existing functionality: Unchanged from the predicate device. Diagnostic functionality: Unchanged from the reference device

Feature/Function	Predicate Device: Care Orchestrator K181053	Reference Device: Sleepware G3 with Somnolyzer Inside, K142988	Subject Device: Care Orchestrator with Home Sleep Testing (Care Orchestrator with HST)	Similarity to Predicate
	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.	indicated for use with adult patients only.	received from compatible monitoring devices used to categorize sleep-related events that help aid in the diagnosis of sleep-related disorders. The Home Sleep Testing function of Care Orchestrator is indicated for Adult use only. Care Orchestrator allows read-only access to patients. Care Orchestrator is intended to be used in hospital, institutional, provider, and home care settings.	
Manufacturer	Respironics, Inc.	Respironics, Inc.	Respironics, Inc.	Unchanged from Predicate and reference.
Location of Use	Hospital, institutional provider, and home settings.	Sleep laboratories	Hospital, institutional, provider, home, and sleep laboratory settings.	In comparison to the predicate device, the subject devices add sleep laboratory settings, which are included in the reference device. Only clinical providers will have access to HST functionality.
Patient Population	Dependent on device intended use	Adults only when using scoring algorithms based on the AASM guide.	Diagnostic HST use: Adults only, remaining use dependent on device intended use.	Unchanged from the predicate and reference.
User Population	Clinical Users, Customer Administrators, Product Support Users	Clinical Users	Clinical users, Customer administrators, Product Support Users	Unchanged from the predicate.
Application Type	Cloud-based software program	PC-based software program	Cloud-based software program	Unchanged from the predicate.
Data Storage	Centralized Database	User PC	Centralized Database	Unchanged from the

Feature/Function	Predicate Device: Care Orchestrator K181053	Reference Device: Sleepware G3 with Somnolyzer Inside, K142988	Subject Device: Care Orchestrator with Home Sleep Testing (Care Orchestrator with HST)	Similarity to Predicate
				predicate.
Contraindications	No Contraindications	No contraindications	No Contraindications	Unchanged from the predicate
Software level of concern	Moderate	Moderate	Moderate	Unchanged from predicate

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." The software for this device 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 included software code reviews, automated testing, bench verification testing and labeling review.

VIII. Conclusion

The modified Care Orchestrator with Home Sleep Testing software is substantially equivalent to Care Orchestrator (K181053).