July 10, 2020

Respironics, Inc.
Andy Zeltwanger
Director, Regulatory Affairs
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K200480
Trade/Device Name: DreamStation 2 System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: June 12, 2020
Received: June 12, 2020

Dear Andy Zeltwanger:

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 Michael Ryan
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)*
K200480

Device Name
DreamStation 2 System

Indications for Use *(Describe)*
The DreamStation 2 CPAP/DreamStation 2 Auto CPAP system delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30 kg (66 lbs). It is for use in the home or hospital/institutional environment.

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."

Pursuant to the requirements of 21 CFR Section 807.92(c), this **510(k) summary** is being provided as part of the DreamStation 2 System 510(k) Premarket Notification.

Submitter

510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Official Correspondent	Andy Zeltwanger Director, Regulatory Affairs P : 724-579-6095 E : andy.zeltwanger@philips.com
Date of Preparation	26 February 2020

Device

Proprietary/Trade Name:	DreamStation 2 System
Common/Usual Name:	CPAP System
Device Classification:	II
Classification Name/ Product Code:	Ventilator, Non-Continuous (Respirator), 21 CFR 868.5905, BZD
Primary Predicate Device:	REMSTAR AUTO A-FLEX HT (K131982)
Secondary Predicate Device:	REMSTAR SE (K130077)
Submission Reason:	New Device

Device Description

The DreamStation 2 System uses a microprocessor-controlled blower to treat patients with Obstructive Sleep Apnea (OSA). There are 2 models:

- DreamStation 2
- DreamStation 2 Advanced

Both aforementioned models will be available in two therapy modes: CPAP only and Auto CPAP. With CPAP therapy, the device provides a continuous positive airway pressure throughout the entire therapy session. With Auto CPAP therapy, the device provides a positive airway pressure that automatically adjusts to the patient's needs as various breathing events are detected, such as apneas and hypopneas.

In addition to the therapy modes, the DreamStation 2 System provides several optional features to aid with patient comfort. These patient comfort features include: Ramp Plus, adjustable pressure relief (FLEX), EZ-Start, Opti-Start, and humidification (adaptive and adaptive with heated tube). *Note: some of the features are only available in the DreamStation 2 Advanced model.*

The DreamStation 2 device also features integrated Bluetooth and cellular technology for the transfer of patient management data between the therapy device and Respironics proprietary compliance software, Care Orchestrator.

Indications for Use

The DreamStation 2 CPAP/DreamStation 2 Auto CPAP system delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30 kg (66 lbs). It is for use in the home or hospital/institutional environment.

Comparison of Technological Characteristics with the Predicate Device(s)

Table 5-1. High-Level Comparison of DreamStation 2 Device to Primary and Secondary Predicates

Feature/Function	Device Predicate 1: REMstar Auto A-Flex HT (K131982)	Device Predicate 2: REMstar SE (K130077)	Subject Device: DreamStation 2 CPAP/Auto CPAP	Subject Device: DreamStation 2 Advanced CPAP/Auto CPAP	Similarities and/or Differences
Intended Use	For the treatment of Obstructive Sleep Apnea (OSA)	For the treatment of Obstructive Sleep Apnea (OSA)	For the treatment of Obstructive Sleep Apnea (OSA)	For the treatment of Obstructive Sleep Apnea (OSA)	Same.
Patient Population (age, gender, etc.)	Spontaneously breathing patients >30 kg (66 lbs)	Spontaneously breathing patients >30 kg (66 lbs)	Spontaneously breathing patients >30 kg (66 lbs)	Spontaneously breathing patients >30 kg (66 lbs)	Same.
Principle of Operation	Microprocessor controlled motor blower design	Microprocessor controlled motor blower design	Microprocessor controlled motor blower design	Microprocessor controlled motor blower design	Same.
Product Specific Performance Standards	ISO 17510-1 ISO 8185	ISO 17510-1 ISO 8185	ISO 80601-2-70 ISO 80601-2-74 Note: *ISO 80601-2-70 has since replaced ISO 17510-1 and ISO 80601-2-74 has since replaced ISO 8185.*	ISO 80601-2-70 ISO 80601-2-74 Note: *ISO 80601-2-70 has since replaced ISO 17510-1 and ISO 80601-2-74 has since replaced ISO 8185.*	Same.
Therapy Algorithm and Flex Waveform Comparison	Substantially Equivalent Results	Not Available	Substantially Equivalent Results	Substantially Equivalent Results	Same.
Energy Delivered	Continuous Positive Airway Pressure (CPAP)	Continuous Positive Airway Pressure (CPAP)	Continuous Positive Airway Pressure (CPAP)	Continuous Positive Airway Pressure (CPAP)	Same.

Feature/Function	Device Predicate 1: REMstar Auto A-Flex HT (K131982)	Device Predicate 2: REMstar SE (K130077)	Subject Device: DreamStation 2 CPAP/Auto CPAP	Subject Device: DreamStation 2 Advanced CPAP/Auto CPAP	Similarities and/or Differences
Energy Source	External Switching Power Supply AC Power (Input): 100 – 240 VAC DC Power (Output): 12 VDC	External Switching Power Supply AC Power (Input): 100 – 240 VAC DC Power (Output): 12 VDC	External Switching Power Supply AC Power (Input): 100 – 240 VAC DC Power (Output): 12 VDC Battery Pack Voltage Range (Input): 11.0-14.4 VDC Voltage Range (Output): 11.0-15.0 VDC	External Switching Power Supply AC Power (Input): 100 – 240 VAC DC Power (Output): 12 VDC Battery Pack Voltage Range (Input): 11.0-14.4 VDC Voltage Range (Output): 11.0-15.0 VDC	Similar. Subject device includes additional power source via a battery pack.
Modes of Operation	• CPAP • Auto CPAP o Split Night with Auto CPAP o Auto-Trial o CPAP-Check	• CPAP	• CPAP • Auto CPAP	• CPAP • Auto CPAP o Auto-Trial o CPAP-Check	Similar. Varies depending on model.
Pressure	4 to 20 cm H_2O	4 to 20 cm H_2O	4 to 20 cm H_2O	4 to 20 cm H_2O	Same.

Feature/Function	Device Predicate 1: REMstar Auto A-Flex HT (K131982)	Device Predicate 2: REMstar SE (K130077)	Subject Device: DreamStation 2 CPAP/Auto CPAP	Subject Device: DreamStation 2 Advanced CPAP/Auto CPAP	Similarities and/or Differences
Pressure Accuracy (Static)	± 0.5 cm H_2O	± 1.0 cm H_2O	For 15mm and 22mm tubing: ± 0.5 cm H_2O For 12mm tubing: ± 1.0 cm H_2O for 12mm tubing.	For 15mm and 22mm tubing: ± 0.5 cm H_2O For 12mm tubing: ± 1.0 cm H_2O for 12mm tubing.	Same. 15mm is same as Primary Predicate (K131982). 12mm is same as Secondary Predicate (K130077).
Pressure Accuracy (Dynamic)	± 1.0 cm H_2O of the pressure values established during verification of the Static Pressure accuracy	Device: ± 2.0 cm H_2O Device w/ Humidifier (22mm Tubing): ± 2.0 cm H_2O Device w/ Humidifier (15mm Tubing): ± 2.5 cm H_2O	For 15mm and 22mm tubing: ± 1.0 cm H_2O For 12mm tubing: ± 2.0 cm H_2O	For 15mm and 22mm tubing: ± 1.0 cm H_2O For 12mm tubing: ± 2.0 cm H_2O	Same. 15mm is the same as Primary Predicate (K131982). 12mm the same Secondary Predicate (K130077).

Table 5-2. High-Level Comparison of Subject Heated Tube (15mm and 12mm) to Predicate Device

Feature/Function	Tube Predicate: REMstar Auto A-Flex HT (K131982)	Subject Device: 15mm Heated Tube and 12mm Heated Tube	Similarities and/or Differences
Intended Use	The heated tube is used, along with the heated humidifier, to control the provided humidification. This is accomplished by controlling the temperature of the air in order to ensure that it does not cool down prior to reaching the mask.	The heated tube is used, along with the heated humidifier, to control the provided humidification. This is accomplished by controlling the temperature of the air in order to ensure that it does not cool down prior to reaching the mask.	Same.
Target Patient Population	Patients weighing more than 66 lb (30 kg)	Patients weighing more than 66 lb (30 kg)	Same.
Energy Used or Delivered	Due to the wire resistance, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. As a result, the air passing through the tubing is warmed to or above the dew point (of the air existing the humidifier) reducing or eliminating water condensation and/or pooling of water in the breathing circuit. The raising of the gas temperature does not exceed	Due to the wire resistance, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. As a result, the air passing through the tubing is warmed to or above the dew point (of the air existing the humidifier) reducing or eliminating water condensation and/or pooling of water in the breathing circuit. The raising of the gas temperature does not exceed	Same.

Feature/Function	Tube Predicate: REMstar Auto A-Flex HT (K131982)	Subject Device: 15mm Heated Tube and 12mm Heated Tube	Similarities and/or Differences
	41°C.	41°C.	
Mode of Action	Applied voltage through heating wires	Applied voltage through heating wires	Same.
Power Source	Power supplied by attached therapy device	Power supplied by attached therapy device	Same.
Tube Diameter (inner)	15 mm	15mm and 12mm	Similar. **Modification:** Addition of 12mm Tubing (Heated and Non-Heated)

Performance Testing Data

Non-Clinical Tests

Performance Testing
Appropriate testing was completed on the DreamStation 2 System to address: all device requirements, any mitigations required per the risk assessment, to show substantial equivalence to the predicate(s), and lastly to provide reasonable assurance of safety and efficacy.

Software Testing
The DreamStation 2 software was developed following IEC 62304:2015, "*Medical Device Software – Software Life Cycle Processess"*. Software verification and validation testing was performed on the DreamStation 2 System based on the product requirements. Testing was conducted and documentation has been 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*", issued May 2005.
This software is considered to have a "Moderate" level of concern, since prior to mitigation of hazards, a failure of the device could potentially result in minor injury to patient or user of the device. Additionally, a malfunction of, or a latent design flaw in the device, could lead to a delay of appropriate medical care that could potentially lead to a minor injury.
The testing included system level testing to verify all required functionality of the DreamStation 2 System.

Biocompatibility Testing
The biocompatibility evaluation, for the DreamStation 2 System, 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*",ISO 10993-1 "*Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*", and ISO 18562-1 "*Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications – Part 1: Evaluation and Testing within a Risk Management Process*", as recognized by FDA. The DreamStation 2 System has proven to be biocompatible when tested in its final, finished, form to both ISO 10993-1:2018 and ISO 18562-1:2017.

General Safety, Electrical Safety and Electromagnetic Compatibility (EMC)
General Safety, Electrical Safety, and Electromagnetic Compatibility testing was conducted on the DreamStation 2 System. 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 60601-1-11:2015
- ISO 80601-2-61: 2011
- ISO 80601-2-70: 2015
- ISO 80601-2-74: 2017

Human Factors/Usability

The DreamStation 2 System has been found to be safe and effective for the intended users, uses, and use environments. The Human Factors/Usability Engineering process, followed for the development of this device, aligns with IEC 62366-1: 2015, *"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"*, issued February 2016.

Results of following this process, in particular the results of the human factors validation study, indicate that intended users can operate the device safely and effectively, and that residual risk associated with use of the device is acceptable.

Clinical Tests

Clinical tests were not required to demonstrate the safety and effectiveness of the DreamStation 2 System. Safety and efficacy of the DreamStation 2 System has been established via non-clinical tests.

Substantial Equivalence Conclusion

Based upon the intended use, design, materials, function, side by side analysis with its predicates, and verification and validation testing, it is concluded that the DreamStation 2 System is substantially equivalent to the aforementioned predicate devices. The modifications between the DreamStation 2 System and its predicate devices do not raise any new questions regarding the safety and effectiveness.

This "510k Notification" demonstrates that the DreamStation 2 System is substantially equivalent to its predicate devices, which are currently marketed under the Federal Food, Drug, and Cosmetic Act.