DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 8, 2016

Respironics Inc.
Colleen Witt
Manager, Regulatory Affairs
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K152356
Trade/Device Name: Sapphire
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: Class II
Product Code: BZD, MNS, MNT, CBK, NOU
Dated: December 4, 2015
Received: December 5, 2015

Dear Colleen Witt:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith M.S.
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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)*
K152356

Device Name
Sapphire

Indications for Use *(Describe)*
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 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.

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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Food and Drug Administration
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PRAStaff@fda.hhs.gov

"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."

TAB 5

510(K) SUMMARY

I. Submitter

Official Contact

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Phone: 724-387-4870
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Date of Preparation January 8, 2016

II. Device

Name of Device: Sapphire

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)

III. Legally Marketed Predicate Devices

- K140054 ResScan, ResMed LTD.
- K132371 EasyCare Online, ResMed LTD.

IV. Device Description

Sapphire is a web application that is used to manage patients utilizing compatible sleep and respiratory devices, view therapy data, generate reports and update device settings for applicable therapy devices. Sapphire is intended to be used by healthcare representatives (e.g., Physicians, Clinicians, Durable Medical Equipment providers) in hospital, institutional, provider and home settings. Device data is transferred either wirelessly or from an SD card to a centralized database. A user can view this data through a web based application on their computer.

Specific roles are assigned within Sapphire. Based on these roles and access rights, users can perform the following tasks within Sapphire:

- Add new users with an assigned role to Sapphire
- Add new patients, along with applicable device information, to Sapphire
- Therapy Data Management (including viewing and generating therapy data reports)
- Update a patient's prescription/device settings for non-life support devices
- Configure compliance rules associated with a patient

V. 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 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.

VI. Comparison of Technological Characteristics with the Predicate Device

Sapphire has the following similarities to the legally marketed predicate devices:

- Similar intended use
- Same operating principle
- Similar technologies

Feature/Function	**Predicate Device #1** Device Name: ResScan 510(k) Number: K140054 Manufacturer: ResMed LTD	**Predicate Device #2** Device Name: EasyCare Online 510(k) Number: K132371 Manufacturer: ResMed LTD	**Subject Device** Device Name: Sapphire 510(k) Number: K152356 Manufacturer: Respironics	**Comments**
Indications for Use	ResScan is intended to augment the standard follow-up care of patients by providing transfer of machine and therapeutic information. This includes the ability to remotely change settings in non-life support devices only.	EasyCare Online is a web based solution for healthcare specialists intended to: - Assist in the diagnosis of sleep disordered breathing in adult patients through analysis of data recorded	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 &	Similar to K140054 and K132371. Intended uses have similar intent with respect to transferring device and therapeutic data and changing device settings in compatible non-life support therapy devices.

	It is intended to be used by Clinicians in conjunction with ResMed compatible therapy devices, using ResMed's proprietary communications protocol.	by an EasyCare Online compatible home sleep test device. - Transfer and display, usage and therapeutic information that has been transmitted remotely from the patient's therapy device located in the home. It is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed therapy device for the treatment of obstructive sleep apnea or respiratory insufficiency. EasyCare Online also provides remote settings capabilities.	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.	
Application	PC based application	Web based application	Web based application	Equivalent to K132371
Data storage	Data stored on Clinician's computer	Data stored on centralized database	Data stored on centralized database	Equivalent to K132371.
Functionality	• Patient management • Display therapy data • Generate reports • Settings management (remote	• Patient management • Display therapy data • Compliance reports • Therapy reports	• Patient management • Display therapy data • Generate reports • Settings management for non-life	Equivalent to K140051 Similar to K132371. Sapphire has the same functionality as K132371 with respect to patient management,

	setting change functionality only applies to non-life support devices)	• Settings management • Diagnostic Home Sleep Test Reports	supporting devices	data display, report generating and settings management. Sapphire does not create diagnostic home sleep test reports as was cleared in K132371.
Settings management	Ability to remotely change device settings in non-life support devices only.	Ability to remotely change device settings.	Ability to remotely change device settings in non-life support devices only.	Equivalent to K140051 and K132371.
Reports	• Summary report • Detailed report • Compliance report	• Detailed report • Compliance report • Therapy report	• Detailed Report (includes compliance information)	Similar to K140051 and K132371.

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 Sapphire based on the product requirements. This testing included complete system testing to verify data transfer from therapy devices to Sapphire, through both wireless data transfer and SD card data transfer. Once data was transferred, all tests confirmed that Sapphire 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 applicable therapy device. Verification of cybersecurity requirements implemented within the system architecture were also confirmed for encryption of data at rest and in transit.

The testing of Sapphire verified that all product requirements have been met with passing test results. The verification and validation testing demonstrated comparable safety and effectiveness of the Sapphire system in comparison to the predicate.

Clinical Tests

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

VIII. Conclusion

Sapphire has passed all of the aforementioned non-clinical tests and required no clinical tests in order to demonstrate safety or effectiveness. It is therefore concluded that Sapphire is substantially equivalent to the predicate devices ResScan, ResMed LTD. (K140054) and EasyCare Online, ResMed LTD. (K132371) in terms of safety and effectiveness.