DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 5, 2015

ResMed Ltd.
C/O Ms. Larissa D'andrea
Director, Government and Regulatory Affairs
ResMed Corp
9001 Spectrum Center Boulevard
San Diego, CA 92123

Re: K151901
Trade/Device Name: AirView
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, BZD, MNR, MNS
Dated: September 28, 2015
Received: October 5, 2015

Dear Ms. Larissa D'andrea:

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.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151901

Device Name
AirView

Indications for Use *(Describe)*
AirView 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 by an AirView compatible home sleep device.
- transfer and display machine and therapeutic information that has been transmitted remotely from the patient's therapy device. It is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed therapy device. AirView also provides remote settings capabilities for non-life support devices only.

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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510(k) Summary

[As required Section 807.92(c)]

Date Prepared	2 July, 2015
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Device Trade name	AirView
Device Common name	(Accessory to) Continuous Ventilator
Product codes	73 CBK 73 BZD

	73 MNS 73 MNR
Class	II
Classification/s Name/s	(Accessory to) Ventilator, Continuous, Facility use (21 CFR 868.5895, Product Code 73 CBK) (Accessory to) Ventilator, Non-Continuous, (IPPB) (21 CFR 868.5905, Product Code 73 BZD) (Accessory to) Ventilator, Breathing Frequency Monitor (21 CFR 868.2375, Product Code 73 MNR) (Accessory to) Ventilator, Continuous, Non-Life-Supporting (21 CFR 868.5895, Product Code 73 MNS)
Predicate device(s)	EasyCare Online - 510(k) number (K132371) ResScan - 510(k) number (K140054)
Reason for submission	Expanded Indications for Use

Intended Use

AirView 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 by an AirView compatible home sleep test device.
- transfer and display machine and therapeutic information that has been transmitted remotely from the patient's therapy device. It is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed therapy device. AirView also provides remote settings capabilities for non-life support devices only.

Device Description

AirView is a web application that can transfer, store, analyse, manage, and display machine and therapy data (from ResMed compatible therapy devices) and diagnostic data (from ResMed compatible sleep study devices). The data is transferred from the device either wirelessly through a communications module or with the aid of a data card/USB stick and internet technology to a central database and then displayed on the healthcare professional's computer through a web browser such as Internet Explorer.

The software application enables patient machine and therapy data to be shared across several different user groups for the primary purpose of monitoring patient compliance and home sleep studies. Clinical users and other healthcare specialists can access data with ResMed approved user accounts.

AirView can also be used by the healthcare specialist to remotely change the machine settings of compatible therapy devices. This assists in addressing any clinical issues in a timely manner and providing the necessary patient support. This is restricted to non-life support therapy devices only.

Basis for Determination of Substantial Equivalence

The modified AirView has the following similarities to the previously cleared predicated devices:

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

The modified AirView has the additional compatibility with ResMed CBK therapy devices. This compatibility is limited to the transfer and display of machine and therapeutic information. AirView provides remote setting capabilities for non-life support devices only.

Design and verification activities were performed on the modified AirView as a result of the updated design inputs changes for the inclusion of CBK compatibility into AirView. Verification testing included End-to-End testing to verify data transfer integrity between the CBK therapy devices and AirView, Regression Testing to ensure no existing functionality was impacted, and Side-by-Side testing to compare data output between the modified AirView and the predicate ResScan (K140054). All tests confirmed the product met the predetermined acceptance criteria and demonstrated that the modified AirView is substantially equivalent to the predicate devices, EasyCare Online (K132371) and ResScan (K140054).

The modified version of AirView does not raise new safety or effectiveness concerns.

Feature	EasyCare Online [Primary predicate(K132371]	ResScan predicate(K140054]	Airview (modified)	Comments
Intended Use	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 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.	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. It is intended to be used by Clinicians in conjunction with ResMed compatible therapy devices, using ResMed's proprietary communications protocol	AirView 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 by an AirView compatible home sleep test device. • transfer and display machine and therapeutic information that has been transmitted remotely from the patient's therapy device. It is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed therapy device. AirView also provides remote settings capabilities for non-life support devices only.	Equivalent *The compatibility of adding the CBK therapy device comes from the secondary predicate, ResScan and further clarification to support that remote changing settings is not applicable to ResMed CBK devices*
Functionality	• Centralised database • Reports (Compliance and Therapy) • Settings management • Patient management • Diagnostic Home Sleep Test Reports (HSTR)	• Reports (Compliance and Therapy) • Settings management (non- life support devices only) • Patient management	• Centralised database • Reports (Compliance and Therapy) • Settings management (non-life support devices only) • Patient management • Diagnostic Home Sleep Test Reports (HSTR)	Equivalent

Feature	EasyCare Online [Primary predicate(K132371]	ResScan predicate(K140054]	Airview (modified)	Comments
Data transfer Technology	• Wireless • SD Card/Internet • File upload/Internet	• Serial connection (RS232) • SD Card • USB Stick • Smart Media Card • Smart Card	• Wireless • SD Card/Internet • File upload/Internet • USB Stick/Internet	Equivalent *Combined features*
Therapy settings	• Pressure • Mode • Comfort	• Pressure • Mode	• Pressure • Mode • Comfort	Equivalent
Patient information	• Mask Leak • AHI • Pressure • Minute Ventilation • Respiratory rate • Mode • EPR Level • Pressure Support Level • Vt • I:E ratio	• Mask Leak • AHI • Pressure • Minute Ventilation • Vt • Respiratory Rate • SpO2	• Mask Leak • AHI • Pressure • Minute Ventilation • Respiratory rate • Mode • EPR Level • Pressure Support Level • Vt • I:E ratio • SpO2	Equivalent *Combined features*
Home Sleep Test Information (HSTI)	• Recording times • Event statistics (including AHI) • Oxy statistics • Pulse statistics	–	• Recording times • Event statistics (including AHI) • Oxy statistics • Pulse statistics	Equivalent

Non Clinical Testing

The modified AirView device was designed in accordance with the applicable requirements in relevant FDA guidance documents and international standards including:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Guidance Off-the-Shelf Software Use in Medical Devices (September 9, 1999)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2, 2014)

- IEC 62304:2006 *Medical device software - Software life cycle processes*
- IEC 62366: 2007 *Medical devices - Application of usability engineering to medical devices*
- EN ISO 14971: 2012 *Medical devices — Application of risk management to medical devices.*

Design and verification activities were performed on the modified AirView as a result of the updated design inputs changes for the inclusion of CBK compatibility into AirView. Verification testing included End-to-End testing to verify data transfer integrity between the CBK therapy devices and AirView, Regression Testing to ensure no existing functionality was impacted, and Side-by-Side testing to compare data output between the modified AirView and the predicate ResScan (K140054). All tests confirmed the product met the predetermined acceptance criteria and demonstrated that the modified AirView is substantially equivalent to the predicate devices, EasyCare Online (K132371) and ResScan (K140054).

The modified version of AirView does not raise new safety or effectiveness concerns.

Clinical Testing

Clinical testing was not deemed necessary. AirView only obtains machine and therapy data from therapeutic devices for which clinical trials have already been conducted, or compared with previous predicate comparison test results.

Conclusion

The indications for use, technological characteristics and principles of operation are similar or the same as the predicate devices. Performance data demonstrated that the modified device is as safe and effective as the predicate devices. Thus the modified AirView is substantially equivalent to the predicate devices, EasyCare Online (K132371) and ResScan (K140054).