K140159

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510(k) Summary – S9 WANDA VPAP ST

Required	By section 807.92 (c)
Date Prepared	16th June, 2014
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Classification Reference	(21 CFR 868.5905 Product code 73 BZD)
Product Code	73 BZD
Class	II
Common/Usual Name	Non continuous ventilator (IPPB).
Proprietary Name	S9 WANDA VPAP ST
Predicate Device(s)	S9 VPAP ST (K102513)
Reason for submission	New Device

Indication for Use

The S9 WANDA VPAP ST is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb (30 kg). It is intended for use in the hospital and home.

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate device [(S9 VPAP ST (K102513)].

- Same intended use
- Same operating principle
- Similar technologies
- Same manufacturing process

The S9 WANDA VPAP ST retains the same operating/technologies/manufacturing characteristics cleared in the S9 VPAP ST (K102513). The main differences between the S9 WANDA VPAP ST and the predicate device (S9 VPAP ST) include: the interface of the flow generator with the humidifier; updated operating system; minor material changes; and the addition of wireless data transfer.

Design and Verification activities were performed on the S9 WANDA VPAP ST device as a result of the risk analysis and design requirements. All tests confirmed the product met the predetermined acceptance criteria. The S9 WANDA VPAP ST complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Draft Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for Home Use - Document Issued on: December 12, 2012
- FDA Draft Guidance document "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff" - Document Issued on: August 13, 2013
- Reviewer Guidance for Premarket Notification Submissions, ARDB, CDRH, FDA, November 1993.

Clinical Testing

Bench testing alone is sufficient to demonstrate Substantial Equivalence. Treatment algorithms remain unchanged from the predicate device (K102513).

Non-Clinical Testing

Side-by-Side bench testing was performed to verify that the S9 WANDA VPAP ST met the requirements of the S9 WANDA VPAP ST System Specification, and compare the results to the predicate device [(S9 VPAP ST (K102513)].

This bench testing included testing the performance of each therapy mode which included:

- Pressure stability
- Response to apneas
- Response to flow limitations and snore.
- Reporting of Closed Airway Detection (CAD)

A breathing machine simulates patient breathing patterns, which results in the Flow Generator responding to provide the therapy mode pressure. The clinical Pass/Fail requirements are traced to the S9 WANDA VPAP ST System Specification and to the predicate device's performance.

This performance testing demonstrate successful implementation of therapy modes into the S9 WANDA VPAP ST

Standards Testing

The S9 WANDA VPAP ST has been tested to appropriate standards and other applicable requirements. The S9 WANDA VPAP ST with integrated heated humidifier was designed and tested according to:

- IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-11 Edition 1.0: 2010, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. (General)
- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 62304:2006 Medical device software – Software life cycle processes
- IEC 62366:2007 Medical devices – Application of usability engineering to medical devices
- ISO 8185:2007 Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems
- ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process

Biocompatibility Testing

Materials used in the construction of components that contact the heated humidified gas pathway are classified as permanent "external communicating devices" (with tissue/bone/dentin). The appropriate biological tests conducted and passed for these components, in accordance with FDA guidance #G95-1 were:

- ISO 10993-3 Genotoxicity,
- ISO 10993-5 Cytotoxicity,
- ISO 10993-6 Implantation and
- ISO 10993-10 Sensitization & Irritation.

Testing for particulate matter and volatiles demonstrated compliance to EPA requirements.

Device Description

S9 WANDA VPAP ST System is similar to the predicate device (S9 VPAP ST (K102513)). Key features include: in-line power supply; integrated humidifier; tubing; colour LCD; and simple controls. The S9 WANDA VPAP ST contains a Micro-processor controlled blower system that generates Continuous Positive Airway Pressure (CPAP) from 3-25 cmH_2O as required to maintain an "air splint" for treatment of OSA. The system comprises the flow generator, patient tubing, mask (patient interface) and humidifier.

The S9 WANDA VPAP ST flow generator includes the same therapy modes as the S9 VPAP ST system (K102513) predicate device. These base therapy modes include:

- CPAP and CPAP with expiratory pressure relief (EPR) modes – the device delivers a continuous positive airway pressure throughout the therapy session
- Bilevel mode – the flow generator augments any breath initiated by the patient by detecting the onset of inspiration or expiration and delivering the set Inspiratory Positive Airway Pressure (IPAP) and Expiratory Positive Airway Pressure (EPAP)
- VAuto mode - the mean air-way pressure (between IPAP and EPAP) will alter based upon breathing events

The functional characteristics of the S9 WANDA VPAP ST system includes all the clinician and user friendly features of the predicate device which have been verified during usability studies in accordance with IEC 62366 Medical devices - Application of usability engineering to medical devices.

Characteristics (differences) between predicate and new device

Flow Generator comparison

Characteristic	Predicate S9 VPAP ST (K102513)	New Device (S9 WANDA VPAP ST)	Comments
Indication for use	The S9 VPAP ST is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb (30 kg). The S9 VPAP ST is intended for use in the hospital and home.	The S9 WANDA VPAP ST is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb (30 kg). It is intended for use in the hospital and home.	Equivalent *Simplified - Intent of IFU remains unchanged*
Performance			
Flow Generator operating system/controller	Micrium uC/OS-II Software/digital	Microchip STM32F405ZG micro–controller with ARM 32-bit Cortex™-M4 CPU Software/digital	Equivalent: *Updated micro in line with latest technologies for micro-controller chip-sets and CPU appropriate for processing power needed for this device.*
Flow generator weight	1.7lb	2.5lb	Equivalent *Includes humidifier internal to the Flow Generator (combined weight of humidifier and flow generator)*
Dimensions H x W x D (inches)	Flow generator unit: 3.4 x 5.5 x 6.0	Flow generator unit: 4.5 x 9.6 x 6.0	Equivalent *Accounts for inclusion of the humidifier with larger width*
Data transfer medium	SD Card	SD Card Wireless	Equivalent: *Wireless data transfer is equivalent to EasyCare Online (K132371). EasyCare Online is indicated for compatibility with ResMed therapy devices.*

Humidifier comparison

Characteristic	Predicate S9 VPAP ST with H5i (K102513)	S9 WANDA VPAP ST Humidifier	Comments
Indication for use	Indicated for the humidification of the air delivered from ResMed compatible CPAP therapy devices	—	Equivalent: *Humidifier is completely integrated- separate manual is no longer required. Relevant information is included in the User Guide. Refer to Appendix I*
Humidifier Performance			
Humidifier output for more than 8 hours	12.7mg/L @ 20cm H_2O (50 L/min)	12.0mg/L @ 20cm H_2O (50 L/min)	Equivalent: *The difference is not clinically significant and acceptance criteria was met (refer to bench testing (section 18)).*
Size	96 mm (H) x 145 mm (W) x 153 mm (L)	N/A	Equivalent *Humidifier is now internal to the Therapy Device*
Weight	0.55 kg (including Docking station)	N/A	Equivalent *Humidifier is now internal to the Therapy Device*

The differences between the predicate [(S9 VPAP ST (K102513)] and S9 WANDA VPAP ST does not raise new questions of safety or effectiveness.

Conclusion

The S9 WANDA VPAP ST is substantially equivalent to the predicate device [(S9 VPAP ST (K102513)].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

June 17, 2014

ResMed Ltd.
Jim Cassi
Vice President, Quality Assurance Americas
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San Diego, CA 92123

Re: K140159
Trade/Device Name: S9 WANDA VPAP ST
Regulation Number: 21 CFR 868.5905
Regulation Name: Non Continuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: May 6, 2014
Received: May 12, 2014

Dear Mr. Cassi:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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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 on last page.

510(k) Number *(if known)*

Device Name
S9 WANDA VPAP ST

Indications for Use *(Describe)*
The S9 WANDA VPAP ST is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb (30 kg). It is intended for use in the hospital and home.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S
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