K140279

JUL 3 1 2014

510(k) Summary

Required	By section 807.92 (c)
Date Prepared	31st July, 2014
Owners Name	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153, Australia
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Product Code	73 BZD
Class	II
Classification Reference	(21 CFR 868.5905 Product code 73 BZD)
Common/Usual Name	Non continuous ventilator (IPPB).
Proprietary Name	S9 Greenhills
Predicate Device(s)	S9 VPAP Adapt (K113801)
Reason for submission	New Device

Indication for Use

The S9 Greenhills is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing.

It is intended for home and hospital use.

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate devices.

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

Design and Verification activities were performed on the S9 Greenhills System as a result of the risk analysis and design requirements. All tests (predicate bench testing) confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device has not altered the safety and effectiveness of CPAP/Bilevel treatment for patients with Obstructive Sleep Apnoea (OSA), central and/or mixed apneas, or periodic breathing who weigh more than 66 lb (>30 kg).

Predicate bench testing and clinical studies were used to show substantial equivalence between the S9 VPAP Adapt (K113801) and S9 Greenhills.

The new device 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- FDA Draft Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for Home Use- Document Issued on: December 12, 2012
- FDA Draft Guidance for Industry and FDA Staff - Radio Frequency Wireless Technology in Medical Devices - Document Issued on: August 13, 2013
- Reviewer Guidance for Premarket Notification Submissions, ARDB, CDRH, FDA, November 1993.

Clinical Testing:

Clinical testing is not required, bench testing alone is sufficient to demonstrate the product remains substantially equivalent to the predicate device S9 VPAP Adapt (K113801).

Non-Clinical Testing:

Side-by-Side bench testing was performed to verify that the S9 Greenhills met the pre-determined pass/fail requirements of the S9 Greenhills System Specification when compared to the predicate devices [S9 VPAP Adapt (K113801)]. This bench testing included testing the performance of each therapy mode which included:

- Pressure stability
- Response to apneas
- Response to flow limitations and snore.
- Response to periodic breathing

A breathing machine simulates patient breathing patterns, which results in the Flow Generator responding in a manner consistent with maintaining the CPAP treatment pressure (CPAP mode) or adjusting the pressure support (PS) in (ASV mode) and adjusting the pressure support (PS) and EPAP in (ASVAuto mode) based upon the patient's condition. The clinical Pass/Fail requirements are traced to the S9 Greenhills System Specification and to the predicate device's performance

The S9 Greenhills has been tested to appropriate FDA consensus standards and other applicable requirements passing all test protocols. The S9 Greenhills with and without the integrated heated humidifier was designed and tested according to:

- 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 for Industry and FDA Staff - Radio Frequency Wireless Technology in Medical Devices - Document Issued on: August 13, 2013
- Reviewer Guidance for Premarket Notification Submissions, ARDB, CDRH, FDA, November 1993.

Device Description

The S9 Greenhills is similar to the predicate device(s), using a blower based positive pressure system with an integrated heated humidifier and heater controller. The device platform is identical to the S9 VPAP Adapt (K113801) and contains a Micro-processor controlled blower system that generates controlled positive airway pressure between 3-25 cmH_2O. The system comprises the flow generator, patient tubing, mask (patient interface) and humidifier.

The S9 Greenhills is a flow generator device designed to provide adaptive servo-ventilation therapy (ASV mode) or (ASVAuto mode) to stabilize a patient's ventilation during sleep. The device continually measures the patient's instantaneous ventilation, and calculates a target ventilation based on to the patient's recent average minute ventilation. It then adjusts the degree of pressure support to servo-control the patient's ventilation to at least equal the target ventilation. The same is true for ASVAuto mode except the EPAP is adjusted to address any obstructive apneas detected.

Therapy modes contained in the S9 Greenhills are CPAP, ASV, and ASVAuto and unchanged from the S9 VPAP Adapt (K102586). They are:

- CPAP mode – the device delivers a continuous positive airway pressure throughout the entire therapy session;
- ASV mode – the device automatically adjusts pressure support in response to the patient's recent average minute ventilation; and
- ASVAuto mode – the device automatically adjusts pressure support in response to the patient's recent average minute ventilation and EPAP level for OSA events.

The functional characteristics of the S9 Greenhills 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.

The functional characteristics of the S9 Greenhills system includes all the clinician and user friendly features of the predicate device.

Characteristic	S9 VPAP Adapt *with* H5i (K113801)	New Device (S9 Greenhills)	Comments
Indication for use	The S9 VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.	The S9 Greenhills is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.	Equivalent *Name change only, same patient population as predicate*
Location of use	Hospital/Home	Hospital/Home	Equivalent
Pressure Range and Treatment Modes			
	4-20 cm H_2O (CPAP) 3-25 cm H_2O (ASV) 3-25 cm H_2O (ASVAuto)	4-20 cm H_2O (CPAP) 3-25 cm H_2O (ASV) 3-25 cm H_2O (ASVAuto)	Equivalent:
RAMP Settings	➢ User selected as "Off" to 45 minutes in 5 minute increments ➢ Max Ramp time set at clinician's discretion	➢ User selected as "Off" to 45 minutes in 5 minute increments ➢ Max Ramp time set at clinician's discretion	Equivalent
System Components	➢ Flow generator ➢ Integrated humidifier (5i) ➢ Mask, air tubing and heated tubing	➢ Flow generator ➢ Humidifier ➢ Mask, air tubing and heated tubing	Equivalent
Power supply	100-240V, 50-60Hz	100-240V, 50-60Hz	Equivalent
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*
Supplemental oxygen	Labeled for use with supplemental oxygen	Labeled for use with supplemental oxygen	Equivalent

Conclusion

The S9 Greenhills is substantially equivalent to the predicate device, S9 VPAP Adapt (K113801).

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

July 31, 2014

ResMed Corp.
C/O Mr. Jim Cassi
Vice President Quality Assurance Americas
9001 Spectrum Center Boulevard
San Diego, CA 92123

Re: K140279
Trade/Device Name: S9 Greenhills
Regulation Number: 21 CFR 868.5905
Regulation Name: Non continuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: June 20, 2014
Received: June 25, 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 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" (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 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Division Director
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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)*

K140279

Device Name
S9 Greenhills

Indications for Use *(Describe)*
The S9 Greenhills is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing.

It is intended for home and hospital use.

The humidifier is intended for single patient use in the home environment and re-use in a 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)

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
2014.07.31 09:55:56 -04'00'

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