

510(k) Summary – S9 VPAP ST

K102513

JAN - 5 2011

Date Prepared 20th Nov, 2010**Official Contact** Mr David D'Cruz – V.P., US Medical & Regulatory Affairs
ResMed Corp.
9001 Spectrum Center Boulevard,
San Diego, CA 92123

Tel: (858) 836-5984**Classification Reference** 21 CFR 868.5905**Product Code** 73 BZD**Common/Usual Name** Non continuous ventilator (IPPB).**Proprietary Name** S9 VPAP ST .**Predicate Device(s)** VPAP ST (K080131).
S8 Aspen with H4i Plus (K091947)
VPAP Tx (K092186)**Reason for submission** New Device

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.

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 VPAP ST System as a result of the risk analysis and design requirements. All bench tests confirmed the product met the predetermined acceptance criteria, this included Pressure, Flattening, Snore, Hypopnea and Apnea tests against the predicate devices using common protocols for both devices. Clinical data for the S9 VPAP ST is not required as the predicate devices have been subjected to clinical trial requirements or validated patient simulation models have been used during the bench testing phases. ResMed has determined that the new device has not altered the safety and effectiveness of CPAP treatment for patients with Obstructive Sleep Apnoea (OSA) who weigh more than 66 lb (>30 kg). The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

Non-Clinical Testing:

This device has been tested to appropriate ISO and IEC standards and other applicable requirements passing all test protocols. The S9 VPAP ST with and without the integrated heated humidifier (H5i) was designed and tested according to:

- 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 60601-1:1988 Ed 2, Medical electrical equipment - Part 1: General requirements for safety
- ISO 17510-1: 2007, Sleep apnoea breathing therapy – Part 1: Sleep apnoea breathing therapy equipment
- ISO 8185:2007, Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems

Device Description

S9 VPAP ST System (S9 VPAP ST *with* H5i) 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, both hardware and firmware come from the S8 Aspen with H4i Plus (K091947) and contains a micro-processor controlled blower system that generates controlled positive airway pressure between 3-25 cmH₂O as required to maintain an "air splint" for effective treatment of OSA. The system comprises the flow generator, patient tubing, mask (patient interface) and humidifier. The S9 VPAP ST contains treatment modes that come from earlier versions of ResMed Bilevel devices, these modes are known as Spontaneous (S Mode), Timed (T Mode), Spontaneous/Timed (S/T Mode) and VAuto Mode. Therapy modes come from the VPAP Tx system (K092186), VPAP ST (K080131) for S, S/T, T and VAuto and CPAP Mode comes from the S8 Aspen (K091947).

Therapy modes contained in the S9 VPAP ST are CPAP, CPAP with EPR, Spontaneous, Spontaneous with Easybreathe, Spontaneous/Timed, Timed, and VAuto.

The functional characteristics of the S9 VPAP ST system includes all the clinician and user friendly features of the predicate devices.

Statement of Safety and Effectiveness

Analysis of comparison of design, function and features of the VPAP Tx system (K092186), VPAP ST (K080131) for S, S/T, T and VAuto and CPAP Mode from the S8 Aspen (K091947) together with the results of testing demonstrates that the S9 VPAP ST to be substantially equivalent to the predicate devices in terms of meeting performance criteria and function as intended.

Conclusion

The S9 VPAP ST is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

ResMed Limited
C/O Mr. David D' Cruz
Vice President Clinical & Regulatory Affairs
ResMed Corporation
9001 Spectrum Center Boulevard
San Diego, California 92123

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Re: K102513
Trade/Device Name: S9 VPAP ST
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 13, 2010
Received: December 15, 2010

Dear Mr. Cruz:

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.

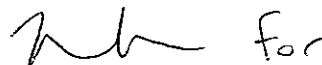
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

K102513

510(k) Number (if known):

Device Name: S9 VPAP ST

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Indication for Use

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Prescription Use X

AND/OR

Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

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L Schmitt
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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