510(k) Summary – S9 VPAP Tx

MAR 21 2013

Date Prepared	16 March 2013
Submitter	Nicole Gaddi Regulatory Affairs Manager ResMed Ltd, Australia
Official Contact	Mr. Jim Cassi V.P., Quality Assurance Americas ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123 USA Tel: (858) 836 6081 Fax: (858) 836 5519
Classification Reference	21 CFR 868.5895
Product Code	73 MNS
Common/Usual Name	Ventilator, continuous, non-life-supporting
Proprietary Name	S9 VPAP Tx
Predicate Device(s)	ResMed, VPAP ST-A (K113288) – Primary ResMed, VPAP ST (K102513) - Secondary ResMed, S9 VPAP Adapt (K113801) - Secondary ResMed, S8 Aspen (K091947) - Secondary
Reason for submission	New Device

Indication for Use

The S9 VPAP Tx is indicated for the treatment and titration of patients with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing. CPAP, S, ST, T and PAC modes are indicated for patients weighing more than 30lb (13 kg); all other modes are indicated for patients weighing more than 66lb (30 kg).

The S9 VPAP Tx is intended to be used in a clinical environment.

Substantial Equivalence

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

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

Design and Verification activities were performed on the S9 VPAP Tx as a result of the risk analysis and design requirements. All tests confirmed the product met the predetermined acceptance criteria. Clinical data for the S9 VPAP Tx 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. 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:

The S9 VPAP Tx has been tested to appropriate FDA consensus standards and other applicable requirements passing all test protocols. The S9 VPAP Tx with and without the optional 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 60601-1:2005, Medical electrical equipment - Part 1: General requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-8:2006, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Materials have been tested in accordance with FDA Guidance documents (G95-1), and ISO 10993 series as defined for "external communicating device", Tissue/Bone/Dentin, contact duration "C".

Device Description

The S9 VPAP Tx is similar to the predicate devices VPAP ST-A (K113288), VPAP ST (K102513), S9 VPAP Adapt (K113801) and S8 Aspen (K091947).

The S9 VPAP Tx provides CPAP, Auto-titrating, Bilevel, VAuto and ASV modes to treat OSA and/or respiratory insufficiency, central or mixed apneas or periodic breathing. This is achieved through the use of a micro-processor controlled blower system that generates airway pressures as required to maintain an "air splint" for effective treatment of OSA and/or respiratory insufficiency.

The S9 VPAP Tx system comprises the flow generator, patient tubing, mask (patient interface) and optional H5i humidifier.

The performance and functional characteristics of the S9 VPAP Tx includes all the clinician and user friendly features of the predicate devices, VPAP ST-A (K113288), VPAP ST (K102513), S9 VPAP Adapt (K113801) and S8 Aspen (K091947).

Conclusion

The S9 VPAP Tx is substantially equivalent to the previously cleared predicate devices.

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

March 21, 2013

Mr. Jim Cassi
Vice President, Quality Assurance Americas
ResMed Corporation
9001 Spectrum Center Boulevard
SAN DIEGO CA 92123

Re: K123511
Trade/Device Name: S9 VPAP Tx
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: February 15, 2013
Received: February 19, 2013

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 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,

Kwame O. Ulmer for

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

Enclosure

Indication for Use

510(k) Number (if known): K123511

Device Name: S9 VPAP Tx

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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)

Albert E. Moyal -S for LS

c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300059331, cn=Albert E. Moyal -S 2013.03.20 16:44:17 -04'00'

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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