K093731

510(k) Summary – VPAP III ST-A

Date Prepared	27th Nov, 2009

MAR 22 2010

Official Contact	Dr Lionel King V.P. of Quality Assurance & Regulatory Affairs ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153 Australia Tel: +61 (2) 8884 1000 Fax: +61 (2) 8884 2004
Classification Reference	21 CFR 868.5895
Product Code	73 MNS
Common/Usual Name	Noncontinuous ventilator (IPPB).
Proprietary Name	VPAP III ST-A
Predicate Device(s)	VPAP III ST-A/Kidsta Mask System (K060105) VPAP III ST-A (K033276) Mirage Micro (K072940)
Reason for submission	Include additional pediatric mask to use with this device.

Indication for Use

The VPAP III ST-A system is intended to provide non-invasive ventilation for adult patients (>66 lbs) and pediatric patients aged 7 years or older (>40 lbs) with respiratory insufficiency or obstructive sleep apnea (OSA). The device is intended for use in the hospital or home.

Substantial Equivalence

The VPAP III ST-A has the following similarities to the previously cleared predicate devices.

- Same intended use
- Same operating principle

- Same technologies
- Same manufacturing process

The VPAP III ST-A was originally cleared for respiratory insufficiency or obstructive sleep apnea (OSA) in an adult target population in K033276. The VPAP III ST-A device was then subsequently cleared for pediatric patients aged 7 years or older (>40lbs) in conjunction with a pediatric (Kidsta) mask (K060105). The addition of the pediatric indication required no physical modification of the VPAP III ST-A device. The VPAP III ST-A flow generator device is essentially unchanged, and therefore has the same flow-cycled, pressure limited operating principle, and uses the same blower assembly, with pressure and flow sensor regulation by microprocessor control technology.

No modification of the cleared VPAP III ST-A (K060105) was required as a result of the addition of the pediatric Mirage Micro for Kidz Mask to the existing device. The Mirage Micro for Kidz Mask is a simple modification of the Mirage Micro (K072940). Compatibility assessment of the Mirage Micro for Kidz Mask with the VPAP III ST-A was performed as a result of the risk analysis and product requirements. Assessment included mask pressure & flow characterization, functional deadspace & CO2 flushing, and anthropometric analysis. Assessment of the new mask characteristics identified that existing device testing for pressure performance, triggering & cycling, and alarm performance remained valid. All testing met the predetermined acceptance criteria. Verification raised no new issues of safety or effectiveness, and ResMed has determined that the new device is Substantially Equivalent to the predicate devices. The Mirage Micro for Kidz mask and the predicate pediatric (Kidsta) mask (K060105) and Mirage Micro mask (K072940) are technologically equivalent being constructed of molded plastic components and laminated fabric headgear with a dual wall silicone interface, and incorporating vent holes to provide continuous air leak to flush out the dead space within the mask and minimize the amount of CO_2 rebreathed by the patient.

ResMed has followed the FDA's Guidance for Industry and FDA Staff document "Pre-market Assessment of Pediatric Medical devices" and applied the principle of FDA's Least Burdensome Approach to demonstrate the Substantial Equivalence of the VPAP III ST-A. We conclude that the existing cleared indications for use can be safely and effectively applied to this device with the additional pediatric mask.

Indication for Use

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Device Description

The VPAP III ST-A is a flow-cycled, pressure-limited ventilator. A blower assembly generates airway pressure. A flow sensor and a pressure sensor in the patient airway feed data on measured flow and pressure into a microprocessor controller, which in turn regulates the blower assembly. The device constantly adjusts air flow to maintain pressure and breath synchronisation, can deliver an operating pressure up to 30cmH2O, and compensates for pressure drop in air tubing. A user interface displays clinical data and enables the operator to set and adjust certain clinical parameters.

The VPAP III ST-A provides a mode of non-invasive positive pressure ventilation (NPPV) called Pressure Support with PEEP, which delivers two treatment pressures (bi-level ventilation). A higher pressure is applied when the patient inhales - IPAP or inspiratory positive airway pressure, and a lower pressure is applied when the patient exhales - EPAP or expiratory positive airway pressure, sometimes referred to as PEEP or positive end-expiratory pressure. The difference between the two treatment pressures represents the amount of pressure support provided to the patient. The VPAP III ST-A has a CPAP mode in which a fixed pressure is delivered, and three bi-level operating modes which determine how the changes between IPAP and EPAP pressures are made: Spontaneous, Spontaneous/Timed and Timed. Patients indicated for Obstructive Sleep Apnea (OSA) are treated through the device providing a splint to keep the airway open, whilst patients indicated for respiratory insufficiency are treating through the device providing breathing assistance through pressure support. The VPAP III ST-A is fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable.

The addition of the Mirage Micro for Kidz Mask provides an additional mask option for pediatric users. The small sized frame and cushion and the small size headgear from the previously cleared Mirage Micro (K072940) has been adopted as the standard configuration for the Mirage Micro for Kidz Mask, to meet the requirements of the pediatric population. The Mirage Micro for Kidz Mask provides therapy through the nose only. The Mirage Micro for Kidz Mask comprises a mask frame and elbow with integrated exhaust vent, mask cushion and laminated headgear. The anthopometric profile of the Mirage Micro for Kidz Mask matches that of the Kidsta Mask cleared in K060105. The patient exposure materials used in the device are predicate materials.

Conclusion

The VPAP III ST-A (with additional pediatric mask) is substantially equivalent to the VPAP III ST-A (K033276), VPAP III ST-A/Kidsta Mask system (K060105) and Mirage Micro (K072940).

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

MAR 22 2010

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

Re: K093731
Trade/Device Name: VPAP III ST-A
Regulation Number: 21CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: January 29, 2010
Received: February 16, 2010

Dear Mr. D'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,

for

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

510(k) Number (if known):

Device Name: VPAP III ST-A

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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)

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

510(k) Number: K093731