K062291

SEP - 8 2006

510(k) Summary – VPAP Malibu

Date Prepared	1st August, 2006
Official Contact	Dr Lionel King V.P., Quality Assurance & Regulatory Affairs ResMed Ltd 97 Waterloo Road North Ryde, NSW 2113 Australia Tel: +61 (2) 9886 5000 Fax: +61 (2) 9878 5517
Classification Reference	21 CFR 868.5905
Product Code	73 BZD
Common/Usual Name	Noncontinuous ventilator (IPPB).
Proprietary Name	VPAP Malibu
Predicate Device(s)	VPAP III (K030843) - Primary AutoSet Spirit (K013843) -Secondary
Reason for submission	New Device

Intended for Use

The VPAP Malibu is indicated for the treatment of adult patients with Obstructive Sleep Apnoea (OSA). 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.

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

Design and Verification activities were performed on the VPAP Malibu as a result of the risk analysis and product requirements. All tests confirmed the VPAP Malibu met the predetermined acceptance criteria. ResMed has determined that the new device is Substantially Equivalent to the predicate devices. The new device complies with the applicable standards and 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)
- FDA Off-the-Shelf Software Use in Medical Devices (September 9,1999)

Intended Use

The VPAP Malibu is indicated for the treatment of adult patients with Obstructive Sleep Apnoea (OSA). It is intended for use in the hospital and home.

Device Description

The VPAP Malibu System is similar to the predicate devices, VPAP III (K030843) and AutoSet Spirit (K013843). The VPAP Malibu provides CPAP, Bilevel and Vset therapy modes to adult patients with OSA. 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.

The system comprises the Flow Generator, HumidAire 2i (K013843), patient tubing, mask (patient interface) and ResLink with Smart Media Card (K024191).

The performance and functional characteristics of the VPAP Malibu system includes all the clinician and user friendly features of the predicate devices, VPAP III (K030843) and AutoSet Spirit (K013843).

Conclusion

The VPAP Malibu is substantially equivalent to the VPAP III (K030843) and AutoSet Spirit (K013843).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2006

ResMed Limited
C/O Mr. David D'Cruz
V.P., Quality Assurance & Regulatory Affairs
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K062291
Trade/Device Name: VPAP Malibu
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: August 1, 2006
Received: August 7, 2006

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.

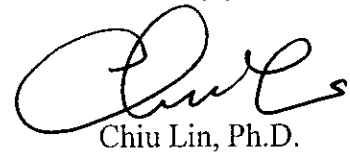
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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 Malibu

Indication for Use

The VPAP Malibu is indicated for the treatment of adult patients with Obstructive Sleep Apnoea (OSA). It is intended for use in the hospital and home.

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)

...sion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number: K062291