K041209

JUL 01 2004

510(k) Summary - S8 Pioneer CPAP System

Date Prepared	Tuesday, May 4th, 2004
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	BZD - Non-Continuous Ventilator
Common/Usual Name	CPAP System
Proprietary Name	S8™ Pioneer CPAP System
Predicate Device(s)	AutoSet Spirit (K013843) S8 Prime (K033841) VPAP III (K030843)
Reason for submission	New Device
Indications for Use	The S8 Pioneer self-adjusting sleep apnea system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The S8 Pioneer self-adjusting sleep apnea system has two treatment modes (AutoSet and fixed-pressure CPAP). The S8 Pioneer system is intended for home and hospital use.

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate device(s).

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

Design and Verification activities were performed on the S8 Pioneer CPAP System as a result of the risk analysis and product requirements. All tests confirmed the product met the acceptance criteria. ResMed has determined that the new device has not altered the safety and effectiveness of CPAP treatment of OSA in adults. The new device complies with the applicable standards and requirements referenced in the FDA guidance documents:

- FDA Reviewer Guidance for Premarket Notifications, November 1993
- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA reviewer's and industry, Guidance for the content of premarket submissions for software contained in medical devices, May 1998

Intended Use

The S8 Pioneer self-adjusting sleep apnea system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The S8 Pioneer self-adjusting sleep apnea system has two treatment modes (AutoSet and fixed-pressure CPAP).

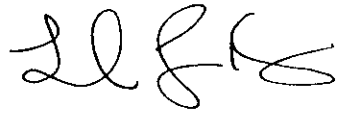
The S8 Pioneer system is intended for home and hospital use.

Device Description

The S8 Pioneer CPAP System is similar to the predicate devices, (AutoSet Spirit, S8 Prime and VPAP III) it is smaller, with a new and improved micro-processor controlled blower system that generates Continuous Positive Airway Pressure (CPAP) from 4-20 cmH_2O as required to maintain an "air splint" for effective treatment of OSA. Treatment modes are self-adjusting, CPAP and CPAP *with* Expiratory Pressure Relief (EPR). CPAP *with* EPR provides a comfort to patients who experience difficulty in breathing out against CPAP during the expiratory phase.

The system comprises the Flow Generator, patient tubing, mask (patient interface) and Smart Card (SC) Module or DB9 Adapter for receiving and sending data.

The performance and functional characteristics of the S8 Pioneer CPAP system includes all the clinician and user friendly features of the predicate devices, Autoset Spirit, S8 Prime and VPAP III.



Dr Lionel King
V.P., Quality Assurance & Regulatory Affairs
ResMed.

Tuesday, May 04, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 01 2004

ResMed Limited
C/O Mr. David D'Cruz
Vice President, Clinical Regulatory Affairs
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K041209
Trade/Device Name: ResMed S8 Pioneer CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: May 4, 2004
Received: May 10, 2004

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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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: S8 Pioneer

Indications for Use:

The S8 Pioneer self-adjusting sleep apnea system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The S8 Pioneer self-adjusting sleep apnea system has two treatment modes (AutoSet and fixed-pressure CPAP).

The S8 Pioneer system is intended for home and hospital use.

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

510(k) Number: K041209

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)