K033914

APR 2 2 2004

510(k) SUMMARY—Oxygen Diverter Valve

Submitter Name:	ResMed Corporation
Submitter Address:	14040 Danielson Street Poway, CA 92064-6857
Contact Person:	David D'Cruz Vice President, Regulatory and Clinical Affairs for the Americas
Phone Number:	(858) 746-2238
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Date Prepared:	December 16, 2003
Device Trade Name:	Oxygen Diverter Valve
Device Common Name:	Oxygen Diverter Valve
Classification Name:	Accessory for Ventilator, Passive exhaust port
Predicate Devices:	1: K963250 Pressure Valve 2: K982530 Mirage Full Face Mask
Device Description:	The Oxygen Diverter Valve is an in-line one-way valve that is intended to prevent oxygen or water in the patient circuit from back flowing into a CPAP or Bilevel Flow

	Generator when the unit is not operating. The Oxygen Diverter Valve incorporates a silicone membrane that seals against the outer housing to vent any backflow to the atmosphere when the pressure drops of the CPAP or Bilevel Flow Generator drops below 2.0cm H_20. The principle of operation is the same as used in the Full Face Mask Anti-asphyxia valve (510(k) number K982530), the difference being in application – in the Full Face Mask, the valve is used to vent CO_2 to atmosphere to prevent patient rebreathing.
Intended Use:	The **Oxygen Diverter Valve** is an accessory to a CPAP or Bilevel Flow Generator intended to prevent the backflow of oxygen or water when the unit is not operating
Device Technological Characteristics and Comparison to Predicate Device(s):	The device function is the same as the Pressure Valve (K963250), which is to prevent the backflow of oxygen or water when the unit is not operating. The Oxygen Diverter Valve (ODV) is a simple modification of the Anti-Asphyxia Valve (AAV) that was FDA cleared as part of the Mirage Full Face Mask 510(k) submission (K982530). The modification is to reverse the genders of patient side and flow-generator side connectors to allow the Oxygen Diverter Valve to be connected, inserted between the flow generator and the air tube. This valve is not a medical device in and of itself, but an accessory to the flow generator system. The Oxygen Diverter Valve will be used in combination with an existing T-piece for introduction of supplemental oxygen.
Performance Data:	Performance testing has been conducted to ensure the safety and effectiveness of the Oxygen Diverter Valve. Tests performed include: • Effectiveness of intended use to prevent oxygen backflow • Activation and Deactivation Pressure • Deactivation Pressure during Therapy • Pneumatic performance characteristics: Impedance added during therapy • Leak rate and pressure range

- Effectiveness of its intended use to divert water
- Effectiveness of oxygen diversion after wetting
- Lifetime testing
- Environmental testing, and
- System Compatibility

Conclusion: Based upon the discussions above, performance studies, documentation in the appendices, and the proposed device labeling, the **Oxygen Diverter Valve** is substantially equivalent to the identified predicate devices in terms of intended use, safety, and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2004

Mr. David D'Cruz
Resmed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K033914
Trade/Device Name: Oxygen diverter valve, CPAP accessory
Regulation Number: 21 CFR 868.5905
Regulation Name: Ventilator, non-continuous
Regulatory Class: II
Product Code: BZD
Dated: March 12, 2004
Received: March 15, 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,

for 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

510(k) Number (if known): K033914

Device Name: Oxygen Diverter Valve

Indications for Use:

The **Oxygen Diverter Valve** is an accessory to a CPAP or Bilevel Flow Generator intended to prevent the backflow of oxygen or water when the unit is not operating.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Ilma M. Pinto

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

510(k) Number: K033914

Prescription Use	✓	OR	Over-The-Counter Use	

(Per 21 CFR 801.109)

(Optional Format 1-2-96)