K031047

AUG 19 2003

3 510(K) SUMMARY

510(k) SUMMARY—Mirage Vista™ Mask

Submitter Name:	ResMed Corp.
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Contact Person:	Roger Kotter, QA&RA Director
Phone Number:	(858) 746 2400
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Date Prepared:	March 28, 2003
Device Trade Name:	Mirage Vista™ Mask
Device Common Name/ Classification Name:	Nasal Mask
Predicate Devices:	Modular Nasal Mask K961783

Device Description:

The Mirage Vista™ mask has an unobtrusive design, which increases the patient's field of vision and allows wearing of glasses whilst the mask is in use. The new design reduces the perceived size and weight of the mask when compared to the predicate mask.

Intended Use:

The Mirage Vista™ mask is an accessory to a non-continuous ventilator (respirator), intended for multiple-patient use for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinical, and home environments.

Device Technological Characteristics and Comparison to Predicate Device(s):

The Mirage Vista™ mask is strapped to the patient's face covering the nose, and connected via tubing to a CPAP or bi-level flow generator. Positive pressure ventilation is thus applied to the lungs in a non-invasive manner.

Mirage Vista™ mask comes in one frame size and two cushion sizes (standard and deep).

The Mirage Vista™ mask is substantially equivalent to the Modular mask. The two masks have the same intended use except reuse (the Mirage Vista™ mask is a multiple-patient use mask, whereas the Modular mask is a single-patient use mask); the same operating principle; the same technological characteristics; and the same type of manufacturing process.

Performance Data:

The Mirage Vista™ mask was tested to determine the pressure-flow characteristic, functional dead space (CO_2 re-breathing) and flow impedance. The results of the performance data show that the mask is substantially equivalent to the predicate mask. In addition, the Mirage Vista mask was validated for multiple-patient use.

The materials used for the mask components, which contact the skin and/or the air-path, are either predicate materials (i.e., cleared previously for the same intended use), or are compliant with the ISO 10993 standards.

Conclusion:

The Mirage Vista™ mask is substantially equivalent to the Modular mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2003

ResMed Limited
C/O Mr. Roger Kotter
Quality Assurance & Regulatory Affairs Director
ResMed Corporation
14040 Danielson Street
Poway, CA 92064-6857

Re: K031047
Trade/Device Name: Mirage Vista™ Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 28, 2003
Received: April 2, 2003

Dear Mr. Kotter:

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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 INDICATIONS FOR USE

510(k) Number (if known): K031047

Device Name: **Mirage Vista™ Mask**

Indications for Use:

The Mirage Vista™ mask is an accessory to a non-continuous ventilator (respirator), intended for multiple-patient use for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinical, and home environments.

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

510(k) Number: K031047

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)