K030798

APR 0 9 2003

510(k) SUMMARY—Mirage Activa™ Mask

Submitter Name:	ResMed Ltd
Submitter Address:	97 Waterloo Road, North Ryde NSW 2113, Australia
Contact Person:	David D'Cruz, VP Regulatory & Clinical Affairs US
Phone Number:	(858) 746 2238
Fax Number:	(858) 746 2282
Date Prepared:	March 10, 2003
Device Trade Name:	Mirage Activa™ Mask
Device Common Name/ Classification Name:	Nasal Mask
Predicate Devices:	Modular Nasal Mask K961783
Device Description:	Mirage Activa™ is a respiratory nasal mask using dual cushion design with built-in bellows. It is a single-patient-use interface accessory for use with CPAP and bi-level devices.
Intended Use:	Mirage Activa™ mask is an accessory to a non-continuous ventilator (respirator) intended for single-patient use for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinic, and home environments.

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

The Mirage Activa™ 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 way.

The Mirage Activa™ mask comes in one frame size and three cushion sizes (standard, large and shallow).

The Mirage Activa™ mask is substantially equivalent to the Modular nasal mask. The two masks have the same intended use, operating principle, technological characteristics and manufacturing process. Below is a summary of the similarities and differences in design between the Mirage Activa™ mask and the Modular nasal mask:

- The functional performance parameters of the Mirage Activa™ mask with respect to pressure-flow characteristic, dead space (CO_2 re-breathing) and flow impedance are equivalent with those of the predicate mask, and are aimed at making the mask compatible with existing flow generators.
- The Activa™ mask has a dual wall cushion design with built-in bellows, which allows relative movement of the mask frame while keeping the cushion seal intact. This design ensures improved mask to patient seal as compared to the predicate mask. To increase the mask stability, the Mirage Activa™ mask has a short air tubing made of polyolefin to remove the weight and drag of the main tube from the elbow. The lightweight tube helps lower the center of gravity and hence improve the stability of the mask.
- The Mirage Activa™ Mask incorporates an elbow able to rotate through 360°, which allows free rotation of the air supply tube, similar to the Modular mask. But while the elbow of the Modular mask is not removable, the Mirage Activa™ elbow can be removed to enable easy access for cleaning.
- The Mirage Activa™ elbow incorporates a baffle, which creates a separate channel to improve the exhaust flow and thus reduce CO_2 re-breathing.
- The exhaust vent in the Mirage Activa™ mask is positioned in the elbow, which is similar in layout with the Modular mask. The exhaust vent of the Mirage Activa™ mask is made of silicone, while the exhaust vent of the Modular mask is made of polycarbonate.
- The Mirage Activa™ mask has a cushion clip to attach the cushion to the frame, allowing the patient to remove the cushion for cleaning. The Modular mask does not have a clip to attach the cushion to the mask frame.
- The Mirage Activa™ mask has an adjustable angular forehead support with detachable forehead pads to ensure a better fit for a range of facial profiles and to increase patient comfort. The Modular mask has a fixed forehead support with an adhesive forehead pad.
- The Mirage Activa™ mask has a 2-port cap made of silicone that can be used to seal one or both ports available for connection to pressure sensing tubing. The Modular mask uses polyethylene ports caps.
- The Mirage Activa™ mask has clips for attaching the headgear to the frame to enable fast removal of the mask, which is an improvement to the Modular mask that uses hook tabs.
- The Mirage Activa™ headgear is made of "Breathoprene" fabric for the core structure, which allows the skin to breathe whilst the headgear is worn, whereas the Modular mask headgear is made of "Velstrech" fabric.

Performance Data:

The Mirage Activa™ mask was tested to determine the pressure-flow characteristic, dead space (CO_2 re-breathing) and flow impedance. The results of the performance data show that the mask is substantially equivalent with the unmodified predicate mask.

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 ISO 10993 standards.

Conclusion:

The Mirage Activa™ mask is substantially equivalent to the Modular mask. The changes in design do not affect safety and effectiveness of the Mirage Activa™ mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 9 2003

Mr. David D'Cruz
VP Regulatory & Clinical Affairs
ResMed Ltd.
c/o ResMed Corporation
14040 Danielson Street
Poway, CA 92064-6857

Re: K030798
Trade/Device Name: Mirage Activa Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 11, 2003
Received: March 13, 2003

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,

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

510(k) Number (if known): K030798

Device Name: **Mirage Activa™ Mask**

Indications for Use:

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

(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)

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

510(k) Number K030798