K032916

DEC - 4 2003

3 510(K) SUMMARY

510(k) SUMMARY—Mirage Activa™ Mask

Submitter Name:	ResMed Corp.
Submitter Address:	14040 Danielson Street, Poway CA 92064-6857 USA
Contact Person:	David D'Cruz, VP US Clinical & Regulatory Affairs
Phone Number:	(858) 746 2238
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Date Prepared:	September 15, 2003
Device Trade Name:	Mirage Activa™ Mask
Device Common Name/ Classification Name:	Nasal Mask
Predicate Devices:	K030798 MIRAGE ACTIVA™ MASK (single-patient multiple use) K023244 MIRAGE FULL FACE SERIES 2 (Cidex Plus, Cidex OPA) K023306 MIRAGE FULL FACE SERIES 2 (Sterrad) K023284 MIRAGE FULL FACE SERIES 2 (High Level Thermal) K961783 MODULAR Mask (cleared as part of the VPAP 2 system)

Device Description:

Mirage Activa™ is a respiratory nasal mask using a dual cushion design with built-in bellows. It is a multiple-patient, multiple-use interface accessory for use with CPAP or bi-level devices.

Intended Use:

The Mirage Activa™ mask is an accessory to a non-continuous ventilator (respirator), intended for multiple-patient use for adult patients prescribed continuous positive airway pressure (CPAP) or 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).

FDA cleared the Mirage Activa™ mask as a single-patient, multiple-use device in K030798 using the Modular Mask (K961783) as a predicate device. Resmed is seeking for the Mirage Activa™ mask to be cleared as a multiple patient, multiple use device

Performance Data:

Specific protocols for validating multiple-patient use have been developed by Resmed (following the guidance of AAMI TIR No. 12-1994). These protocols have been reviewed and accepted by the FDA for the Full Face Mask Series 2 (K023244, K023284 and K023306) and represent current state-of-the-art infection control procedures. Resmed has adopted the labeling model from the Full Face series 2 and intends to include the Disinfection Guide provided in Appendix A with the sale of Mirage Activa™ masks.

Conclusion:

The Mirage Activa™ mask is substantially equivalent to the previously cleared predicate masks and can be relabeled for multiple-patient, multiple-use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

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

Re: K032916
Trade/Device Name: Mirage Activa Mask
Regulation Number: 868.5905
Regulation Name: Non-continuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: September 15, 2003
Received: September 22, 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,

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

Indications for Use

510(k) Number (if known): K032916

Device Name: Mirage Activa™ Mask

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number: K032916