3 510(K) SUMMARY

510(k) SUMMARY—Mirage Activa™ Mask

Submitter Name:	ResMed Corp.
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Contact Person:	David D'Cruz, VP US Clinical & Regulatory Affairs
Phone Number:	(858) 746 2238
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Date Prepared:	September 1, 2004
Device Trade Name:	Mirage Swift
Device Common Name/ Classification Name:	Nasal Mask
Predicate Devices:	K032433 Mirage Swift (Nasal Jacks) K980721 Mirage Nasal Mask (cleared as part of the Sullivan Autoset Nasal CPAP Submission) K032916 Mirage Activa Multiple Patient Reuse 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)

Device Description:

The Mirage Swift is designed for adult patients for the delivery of non-invasive ventilatory support using continuous positive airway pressure or bi-level therapy. It is intended for multiple patient re-use and is minimally obtrusive to the user providing a high level of comfort, ease-of-use and seal.

Intended Use:

The Mirage Swift is intended for Multiple Patient Reuse by adult patients (>30 Kg) prescribed continuous positive airway pressure or bilevel therapy for use in home, hospitals or clinics.

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

The Mirage Swift is supported by headgear to allow a seal with the patients nostrils via the nasal cushions, then 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.

The Mirage Swift comes in one frame size and has three nasal cushion sizes.

The Mirage Swift was cleared by FDA in K032433 as a single patient re-use device. The fundamental technological characteristics and scientific principle of the Mirage Swift are unchanged. The indications for use have been extended to include Multiple Patient Reuse. The Mirage Swift is shown to be substantially equivalent to the Mirage Activa and Mirage Full Face mask series 2 masks, cleared by FDA for Multiple Patient Reuse.

Performance Data:

Performance data and rationale are provided in order to demonstrate that the Mirage Swift is substantially equivalent to the Mirage Activa and Mirage Full Face Mask Series 2. The Mirage Swift can therefore be labeled as a multiple patient use device. ResMed has adopted the labeling model from the Mirage Activa and intends to include the Disinfection Guide provided in Appendix A with the sale of Mirage Swift masks.

Conclusion:

The Mirage Swift 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

OCT 8 - 2004

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

Re: K042403
Trade/Device Name: Mirage Swift
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: August 25, 2004
Received: September 3, 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 (240) 276-0120. 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

4 INDICATION FOR USE

510(k) Number (if known):

Device Name: Mirage Swift

Indications for Use:

The Mirage Swift is intended for Multiple Patient Reuse by adult patients (>30 Kg) prescribed continuous positive airway pressure or bilevel therapy for use in home, hospitals or clinics.

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

510(k) Number: K042403

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)