PREMARKET NOTIFICATION

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Submitter Name:	ResMed Ltd
Submitter Address:	97 Waterloo Road, North Ryde NSW 2113, Australia
Contact Person:	Roger Kotter
Phone Number:	(858) 746 2400
Fax Number:	(858) 746 2282
Date Prepared:	September 2002
Device Trade Name:	Mirage Full Face Mask (FFM) Series 2
Device Common Name/ Classification Name:	Face mask
Predicate devices:	Mirage Full Face Mask (FFM) K982530 Mirage Nasal Mask System K984428
Device Description:	Mirage FFM Series 2 is a respiratory mask covering the nose and the mouth. It is a patient interface accessory for use with CPAP and bi-level devices.
Intended Use:	Mirage Full Face Mask (FFM) Series 2 is intended for multiple-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 FFM Series 2 is strapped to the patient's face covering the nose and the mouth, 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 FFM Series 2 comes in three frame sizes (small, medium, large), and two cushion sizes (standard and shallow) for each frame size.

The Mirage FFM Series 2 is substantially equivalent to the Mirage FFM. The two masks have the same intended use. Below is a summary of the similarities and differences in design between the Mirage FFM Series 2 and Mirage FFM:

- The components of Mirage FFM Series 2 are made of the same materials as those of Mirage FFM, with the exception of the headgear and the ports caps.
- The headgear of Mirage FFM Series 2 is made of a Polyurethane-based fabric. The Polyurethane-based fabric is more comfortable, allowing the skin to breathe whilst the headgear is worn.
- Mirage FFM Series 2 has a 5-points headgear connection, whereas Mirage FFM has a 4-points connection headgear. The additional attachment point for the head strap provides enhanced stability.
- Mirage FFM Series 2 has pressure port luer-lock fittings, whereas Mirage FFM has pressure port plugs. The luer-lock fittings provide improved connection. The ports caps material has been changed.
- Mirage FFM Series 2 has two cushion sizes per frame size (standard and shallow), whereas Mirage FFM has only one cushion size per frame size (standard).
- The shape of the elbow retainer was slightly changed in Mirage FFM Series 2 to enable a more user-friendly assembly and disassembly.
- Mirage FFM has been validated for high-level disinfection using the following liquid chemical disinfectants: 3.4% glutaraldehyde solution (e.g. Cidex Plus made by ASP); and 0.08% peroxyacetic acid and 1% hydrogen peroxide (e.g. Cidex PA made by ASP). Mirage FFM Series 2 has been validated for these two liquid chemicals, and, in addition, for sterilization with the Sterrad 100S System made by ASP (K991999).

Performance Data:

The Mirage FFM Series 2 was validated for multiple-patient use, with the following methods:

- High-level disinfection with liquid chemical 3.4% glutaraldehyde solution (e.g. Cidex Plus made by ASP),
- High-level disinfection with liquid chemical 0.08% peroxyacetic acid and 1% hydrogen peroxide (e.g. Cidex PA made by ASP), and
- Sterilization with the Sterrad 100S System made by ASP.

The semi-critical mask components can withstand 15 cycles of high-level disinfection or sterilization. One conditioning cycle consists of: disassembly, cleaning, disinfecting/sterilization, and re-assembly. As an exception, the valve membrane and air tubing cannot be disinfected/ sterilized and therefore must be replaced before reusing on another patient. This is highlighted in the user instructions.

The headgear is a non-critical item, i.e., it comes into contact only with intact skin, and as such it does not require high-level disinfection / sterilization.

Materials used for the mask components in air-path are identical with materials used in predicate mask Mirage FFM.

Conclusion:

The Mirage FFM Series 2 is substantially equivalent to the Mirage FFM. The addition of the sterilization method with the Sterrad 100S System made by ASP does not affect safety and effectiveness of the Mirage FFM Series 2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 7 2002

ResMed Limited.
C/O Mr. Roger Kotter
Senior Director, QA & RA
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K023306
Trade Name: Mirage Full Face Mask Series 2
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: 73 BZD
Dated: September 30, 2002
Received: October 3, 2002

Dear Mr. Kotter:

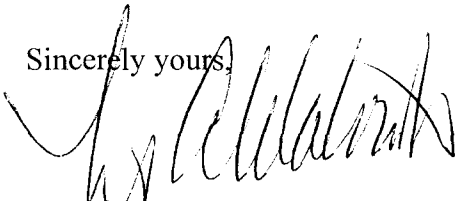
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: **ResMed Ltd**

Device Name: **Mirage Full Face Mask (FFM) Series 2**

510(k) Number (if known): - K023306

INDICATIONS FOR USE:

The Mirage Full Face Mask (FFM) Series 2 is intended for multiple-patient use for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinic, and home environments.

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

510(k) Number: K023306

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-896)