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K063122

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510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared 25th, January, 2007

Official Contact Dr Lionel King,
Vice-President, Global Quality Assurance and Regulatory Affairs

Device Trade Name Mirage Quattro™ Full Face Mask

Device Common Name/ Classification Name Full Face Mask,
Accessory to Noncontinuous Ventilator (IPPB)

Classification 21 CFR 868.5905, 73 BZD (Class II)

Predicate Device Mirage FFM Series 2 (K023244, K023284 and K023306), Mirage Swift (K042403).

Description The Mirage Quattro FFM provides seal such that air flow from a positive pressure source is directed to the patient's nose or mouth. The mask is held in place with adjustable headgear that straps the mask to the face.

Mirage Quattro FFM is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.

Intended Use The Mirage Quattro channels airflow non invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Mirage Quattro is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Mirage Quattro FFM is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital/institutional environment.

Technological Characteristics comparison *Comparison with predicate device, Mirage FFM Series 2:*

The new device and the predicate mask provide seal via dual wall silicone interface. Both masks are offered in various sizes to ensure adequate fit range.

Both the masks incorporate vent holes in the frame to provide continuous air leak to flush out the dead space within the mask and minimize the amount of CO_2 rebreathed by the patient.

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Both the masks include built-in Anti-Asphyxia Valve which in conjunction with the vent holes allow the patient to continue to breathe fresh air in the event of positive air-pressure device failure or deterioration in the therapy being administered. The design of the mask components is such that the incorporation of these vent holes do not interfere with the intended performance of the masks.

Both the masks connect to conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref: ISO 5356-1).

All the components of both the masks are fabricated using materials deemed safe. (ref: ISO 10993).

Both the masks are constructed using molded plastic components and fabric headgear.

The main differences are in the number of components, and their design, geometry and how individual components interface with each other. Both the masks are designed and constructed under ResMed's 21 CFR Part 820 compliant Quality Management System.

Comparison with predicate device, Mirage Swift:

Both the new device and the predicate device can be reused in the hospital/institutional environment. The new device is compatible with an additional method of sterilization when compared to the predicate device.

Clinical Data Use of Full Face Masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the Mirage Quattro FFM, as was the case with the predicate device.

Performance Data The Pressure flow characteristics, functional dead-space, physical dead space and flow impedance of both the new device and the predicate device are substantially equivalent.

Substantial Equivalence Conclusion Mirage Quattro Full Face Mask (FFM) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

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Re: K063122
Trade/Device Name: Mirage Quattro™ Full Face Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: January 25, 2007
Received: January 29, 2007

Dear Mr. 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/industry/support/index.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

Indication for Use

510(k) Number (if known):

Device Name: MIRAGE QUATTRO™ FULL FACE MASK

Indication for Use

The Mirage Quattro channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Mirage Quattro is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Mirage Quattro FFM intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital/institutional environment.

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

(Division Sign-Off)
Division of [illegible] General Hospital, Infection Control [illegible]

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