RESMED

K071808

OCT 10 2007

**510(k) SUMMARY**
*[As required by 21 CFR 807.92(c)]*

**Date Prepared** June 27, 2007

**Official Contact** Mr. David Thomson,
Senior Regulatory Affairs Manager

**Device Trade Name** Mirage Micro™

**Device Common Name/ Classification Name** Vented Nasal Mask;
Accessory to Noncontinuous Ventilator (IPPB)

**Classification** 21 CFR 868.5905, 73 BZD (Class II)

**Predicate Devices** Ultra Mirage II Mask (K050359)
Meridian Nasal Mask (K050142)

**Description** The Mirage Micro provides seal such that airflow from a positive pressure source is directed to the patient's nose. The mask is held in place with adjustable headgear that straps the mask to the face.

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

Mirage Micro is a prescription device supplied nonsterile.

**Intended Use** The Mirage Micro 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 Micro is:
- to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.
- intended for single patient re-use in the home and the hospital/institutional environment.

**Technological Characteristics comparison** *Comparison with predicate Ultra Mirage II*
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 over the extended patient population.

Both the masks incorporate vent holes 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. The design of the mask components is such that the incorporation of these vent holes do not interfere with



ResMed Ltd 1 Elizabeth MacArthur Drive, Bella Vista NSW 2153 Australia Tel: +61 2 8884 1000 Fax: +61 2 8883 3114 ABN 30 003 765 142

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 5356-1:2004)

Both the masks have provisions for connecting oxygen and pressure sensing tubing via luer ports.

Both the masks are constructed using molded plastic components and fabric headgear. All the components of both the masks are fabricated using materials deemed safe. (ref: ISO 10993-1).

The main differences between Micro Mirage and Ultra Mirage II are in the number of components, 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.

The predicate device can be reused by multiple patients in the hospital/institutional environment where as the new device is labeled for single patient reuse.

**Clinical Data**

Use of vented nasal 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 Micro, as was the case with the predicate devices.

**Performance Data**

The CO2 performance the new device and the predicate device are substantially equivalent.

*Comparison with predicate Meridian*

Both the new device and the predicate are designed to operate on the same *standard* flow generator setting. The pressure-flow characteristics and flow impedance of both the new device and the predicate device are substantially equivalent.

**Substantial Equivalence Conclusion**

Mirage Micro is substantially equivalent to the predicate devices:

- it has the same intended use with reduced scope being for single patient reuse;
- it has similar technological characteristics to Ultra Mirage II;
- it does not raise new questions of safety and effectiveness;
- it is at least as safe and effective as the Ultra Mirage II and the Meridian



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2007

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

Re: K071808
Trade/Device Name: MIRAGE MICRO™
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 21, 2007
Received: September 24, 2007

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) 276-0115. 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 MICRO™

**Indication for Use**

The Mirage Micro 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 Micro is:

- to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.
- intended for single patient re-use in the home environment and the hospital/institutional environment.

Prescription Use AND/OR Over-The-Counter Use____
X
(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)



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

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