K081321

OCT 09 2008

Special 510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared	May 07, 2008
Official Contact	David Thomson Regulatory Affairs Director
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 Device	Mirage Micro Mask (K072940)
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 environment and multi-patient re-use in the hospital/institutional environment.
Technological Characteristics comparison	*Comparison with predicate Mirage Micro* The modified 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 does 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 5356-1:2004)

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 masks, including the modification to the swivel color, are fabricated using materials deemed safe. (ref: ISO 10993-1).

Both the modified device and the predicate device can be reused in the hospital / institution environment.

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

Comparison with predicate Mirage Micro
The CO2 performance of the modified device and the predicate device are substantially equivalent.

Both the modified 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 modified device and the predicate device are substantially equivalent.

Substantial Equivalence Conclusion

Modified Mirage Micro is substantially equivalent to the predicate device:

- it has the same intended use;
- it has similar technological characteristics to both predicates;
- it does not raise new questions of safety and effectiveness;
- it is at least as safe and effective as the predicate devices Mirage Micro.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 09 2008

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

Re: K081321
Trade/Device Name: Mirage Micro™
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 19, 2008
Received: October 2, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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): K081321

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 multi-patient reuse in the hospital/institutional environment.

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)

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

510(k) Number: K081321

May 7, 2008