RESMED

K110444

MAR 16 2011

Special 510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared	March 8, 2011
Official Contact	David D'Cruz Vice President, US Medical & Regulatory Affairs 9001 Spectrum Center Blvd., San Diego CA 92123
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 headgear colour of the modified device has changed. The color of the outer layer of the fabric is being changed from dark blue to tan. All other aspects of the device remain unchanged. The modified Mirage Micro is safe when used under the conditions and purposes intended as indicated in the labelling provided with the product. The modified 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 multipatient re-use in the hospital/institutional environment.
Technological Characteristics Comparison	<u>Comparison with predicate Mirage Micro</u> The headgear colour of the modified device has changed. The colour of the outer layer of the fabric is being changed from dark blue to tan. All other aspects of the device remain unchanged. The following technological details are outlined below are provided for completeness only.

	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 masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref: ISO 5356-1:2004) Both masks have provisions for connecting oxygen and pressure sensing tubing via luer ports. Both 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). Both the modified device and the previously cleared 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 The change does not require bench testing as the change has no effect on the technological characteristics when used with a compatible ResMed flow generator.
Performance Data	Comparison with predicate Mirage Micro The headgear performance of the modified device and the previously cleared device are substantially equivalent. Both the modified device and the previously cleared device are designed to perform the same function. As the outer layer of the headgear fabric does not come in to contact with the patient under normal use conditions, ISO 10993-1 is not applicable in this situation.
Substantial Equivalence Conclusion	The modified Mirage Micro is substantially equivalent to the previously cleared 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 previously cleared Mirage Micro (K072940).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Resmed Limited
C/O Mr. David D'Cruz
Resmed Corporation (2183969)
9001 Spectrum Center Boulevard
San Diego, California 92123

MAR 16 2011

Re: K110444
Trade/Device Name: Mirage Micro™
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuos Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 9, 2011
Received: March 11, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Mirage Micro™

Indications 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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schaitkes

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

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