K090490

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

MAY - 6 2009

Date Prepared	February 20th, 2009
Official Contact	Mr. Steven Lubke, Director, Regulatory Affairs
Device Trade Name	Mirage™ Echo
Device Common Name/ Classification Name	Vented Nasal Mask; Accessory to Noncontinuous Ventilator (IPPB)
Classification	21 CFR 868.5905, 73 BZD (Class II)
Predicate Devices	Mirage Micro (K071808, K072940, K081321) Ultra Mirage II Mask (K050359)
Description	The Mirage Echo provides an interface 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 Echo is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product. Mirage Echo is a prescription device supplied non-sterile.
Intended Use	The Mirage Echo channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system. The Mirage Echo is: • to be used by adult patients (> 66 lb/30 kg) 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	*Comparison with predicate Mirage Micro* The new device and the predicate mask, provide a seal via silicone interface. Both masks are offered in various sizes to ensure adequate fit over the extended patient population. Both masks incorporate vent holes to provide continuous air leak to flush out 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 are constructed using molded plastic and silicone

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

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

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

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

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 ECHO, as was the case with the predicate device.

Performance Data

Comparison with predicate Ultra Mirage II
The CO2 performance of the new device and the predicate device are substantially equivalent.

Substantial Equivalence Conclusion

Mirage Echo is substantially equivalent to the predicate devices:

- 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 and Ultra Mirage II

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2009

Mr. David D'Cruz
Vice President, Clinical & Regulatory Affairs
Resmed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K090490
Trade/Device Name: Mirage™ Echo
Regulation Number: 868.5905
Regulatory Class: II
Product Code: BZD
Dated: February 20, 2009
Received: February 25, 2009

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0100. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., M.A.
Acting 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™ Echo**

Indication for Use

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

The Mirage Echo is:

- to be used by adult patients (> 66 lb/30 kg) 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.

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)

February 20, 2009

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

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