510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared	Sept 17th, 2010
Submitter **Official Contact**	Mr. Kim Kuan Lee Mr. David D'Cruz, V.P., US Medical & Regulatory Affairs 9001 Spectrum Center Blvd San Diego CA 92123 USA Tel: (858) 836-5984
Device Trade Name	Mirage™ FX
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 Nasal Mask (K072940) Ultra Mirage II Nasal Mask (K050359) ComfortLite 2 (K082558)
Description	The Mirage FX 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 FX is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product. Mirage FX is a prescription device supplied non-sterile.
Intended Use	*Comparison with predicate ComfortLite 2* The Mirage FX 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 FX is: • to be used by patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed • intended for single-patient reuse in the home environment and multi-patient reuse in the hospital/institutional environment. *The new device and the predicate mask have identical intended uses. Both devices are indicated for the same user population.*
Technological & non clinical performance characteristics	*Comparison with predicate Mirage Micro* *The new device and the predicate mask provide a seal via silicone interface. Both the new and predicate 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 CO2 rebreathed*

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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 the new and predicate devices are constructed using molded plastic and silicone components and fabric / nylon headgear. Components of the new and predicate masks masks are fabricated using materials deemed safe. (ref: ISO 10993-1).

The pressure-flow characteristics and flow impedance of the new devices was bench tested and demonstrated to be substantially equivalent to the predicate device.

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

The main differences between Mirage FX and the predicate 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.

Non clinical performance Data

Comparison with predicate Ultra Mirage II

The CO_2 performance of the Mirage FX has been demonstrated through bench testing to be substantially equivalent to the Ultra Mirage II.

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 FX, as was the case with the predicate devices.

Substantial Equivalence Conclusion

Mirage FX is substantially equivalent to the predicate devices:

- *it has the same, intended use and is indicated for the same user population;*
- *it has similar technological characteristics to the predicates;*
- *it does not raise new questions of safety and effectiveness;*
- *it is at least as safe and effective as the predicate devices.*

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

Mr. David D'Cruz
V.P. US Medical & Regulatory Affairs
ResMed, Limited
9001 Spectrum Center Boulevard
San Diego, California 92123

DEC 28 2010

Re: K102746
Trade/Device Name: Mirage™ FX
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BDZ
Dated: December 20, 2010
Received: December 22, 2010

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 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

Indication for Use

510(k) Number (if known):

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Device Name: **Mirage™ FX**

Indication for Use

The Mirage FX 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 FX is:

- to be used by 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)

17 September, 2010

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K102746