5. 510(k) SUMMARY

K 113127

[As required by 21 CFR 807.92]

Date Prepared	18 October, 2011
Submitter	Ms. Tracey Bullivant, Regulatory Affairs Manager
Official Contact	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 Quattro™
Device Common Name/ Classification Name	Vented Full Face Mask; Accessory to Noncontinuous Ventilator (IPPB)
Classification	21 CFR 868.5905, 73 BZD (Class II)
Predicate Device	Mirage Quattro™ (K063122)
Description	The Mirage Quattro provides an interface such that airflow from a positive pressure source is directed to the patient's nose and mouth. The mask is held in place with adjustable headgear that straps the mask to the face. The Mirage Quattro is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product. The Mirage Quattro is a prescription device supplied non-sterile.
Intended Use	The Mirage Quattro 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 Quattro is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed. The Mirage Quattro is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital/institutional environment.

Comparison of Technological Characteristics

Comparison with previously cleared Mirage Quattro

The modified device and the previously cleared mask both 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 vents to provide continuous air flow to flush out and minimize the amount of CO2 rebreathed by the patient. The design of the mask components is such that the incorporation of these vents does not interfere with the intended performance of the masks. Both masks also contain an anti-asphyxia valve (AAV) to enable the patient to breathe fresh air in the event that airflow from the flow generator is impeded.

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 moulded plastic and silicone components and fabric / nylon headgear. All the components of both masks are fabricated using materials deemed safe (ISO10993-1).

Both the modified device and the previously cleared device are designed to operate on the same *Full Face* ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both the modified device and the predicate device are identical.

Both the modified device and the previously cleared device can be reused in the home and hospital / institution environment.

Clinical Data

Use of vented 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 modified Mirage Quattro, as was the case with the previously cleared Mirage Quattro device.

Performance Data

Comparison with previously cleared Mirage Quattro

The CO_2 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 operate on the same flow generator settings as specified in the User Guide. The only difference is an extension in the therapy pressure range from 4-20cmH_2O to 4-40cmH_2O. Verification testing of the modified device did not raise any new questions of safety and efficacy.

Substantial Equivalence Conclusion

The modified Mirage Quattro is as safe and effective as the previously cleared Mirage Quattro device:
- it has the same intended use;
- it has identical technological characteristics to the previously cleared device;
- the modified device did not raise any new questions of safety or effectiveness;
- it is at least as safe and effective as the previously Cleared Mirage Quattro (K063122).

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

JAN - 6 2012

ResMed Limited
C/O Mr. David D'Cruz
Vice President, US Medical Regulatory Affairs
ResMed Corporation
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K113127
Trade/Device Name: MIRAGE QUATTRO™ FULL FACE MASK
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 2, 2011
Received: December 7, 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Division 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 QUATTRO™ FULL FACE MASK

Indication for Use

The Mirage Quattro 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 Quattro is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Mirage Quattro is intended for single patient re-use in the home environment and/or 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)

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

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