K123979

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

FEB 2 7 2013

Date Prepared	February 25th, 2013
Submitter Name	Mr. Jean-Nicolas Boudaud
Official Contact	Mr. Jim Cassi Vice President - Quality Assurance Americas 9001 Spectrum Center Blvd San Diego CA 92123 USA Tel: (858) 836 6081
Device Trade Name	Quattro™ Air
Device Common Name/ Classification Name	Vented Full Face Mask; Accessory to Noncontinuous Ventilator (IPPB)
Classification	21 CFR 868.5905, 73 BZD (Class II)
Predicate Devices	Mirage Quattro (K063122) Mirage FX (K102746) Ultra Mirage FFM (K023244)
Description	The Quattro Air is an externally placed mask covering the mouth and the nose of the patient. It provides a seal such that positive pressure from a positive pressure source is directed to the patient's nose and/or mouth. It is held in place with an adjustable headgear that straps the mask to the face. Quattro Air is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product. Quattro Air is a prescription device supplied non-sterile.
Intended Use	The Quatto Air is: • to be used by patients (> 66 lbs / 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 the predicate Mirage Quattro* The new device and the predicate mask, provide a seal around the nose and the mouth 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 re-breathed 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 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.

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

Both the new mask and the predicate device are designed to operate on the same "Mir Full" or "Full Face" ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both devices are very similar.

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

The main differences between Quattro Air and the predicate mask Mirage Quattro are in the number of components, their geometry and how individual components interface with each other. These technological characteristics do not impact the fundamental operating principle of the device nor its therapeutic effect. Performance data is available to show that no new questions of safety or efficacy have been raised as a result of these differences.

Technological Characteristics comparison

Comparison with predicate Mirage FX
The construction of the Quattro Air mask components and the way they interface with each other are very similar to that of the predicate device Mirage FX.

Non-Clinical Testing Data

Comparison with predicate devices
The CO_2 performance of the new device was tested to ensure the mask design provides adequate venting to flush out the expired CO_2. The testing included physical and functional dead-space measurements. The device satisfied the pass/fail criteria and was shown to be substantial equivalent to the predicate devices.

The Anti-Asphyxia Valve (AAV) performance was tested to ensure the patient can continue to breathe fresh air if ever the airflow from the flow generator is impeded. The device satisfied the pass/fail criteria and was shown to be substantial equivalent to the predicate devices.

The pressure-flow characteristics and through impedance of the mask were tested to ensure clinicians are able to prescribe the appropriate therapy using the new device. The device satisfied the pass/fail criteria and was shown to be substantial equivalent to the predicate devices.

The mechanical integrity and performance of the new device was tested during normal use and reasonable abuse scenarios. The

device was also tested to demonstrate that the mask can withstand the effects of storage temperature, humidity and transportation shock & vibration. The device satisfied the pass/fail criteria based on defined system specifications and FDA Guidance and was shown to be substantial equivalent to the predicate devices.

Validation of the cleaning of the device was completed to establish that the device can be safely reused by a single patient, or used for multipatient re-use in the hospital/institutional environment following validated disinfection protocols. After 20 cycles of cleaning/disinfection in accordance with the methods described in the cleaning/disinfection guide, the device has been shown to function as intended. The device satisfied the pass/fail criteria and was shown to be substantial equivalent to the predicate devices.

In accordance with the present version of ISO 10993-1, all externally communicating components with either prolonged (24 hours – 30 days) or permanent (>30 days) tissue contact were validated with cytoxicity, sensitization, irritation, genotoxicity and implantation tests as required. Components with skin contact underwent cytotoxicity, sensitization and irritation testing. The device satisfied the pass/fail criteria and was shown to be substantial equivalent to the predicate devices.

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 new Quattro Air mask, as was the case with the predicate devices.

Substantial Equivalence Conclusion

The new Quattro Air is as safe and effective as the predicate devices:

- it has the same intended use;
- it has identical technological characteristics to the predicate devices;
- it does not raise any new questions of safety or 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 Center – WO66-G609
Silver Spring, MD 20993-0002

February 27, 2013

ResMed Limited
C/O Mr. Jim Cassi
Vice President - Quality Assurance Americas
ResMed Corporation
9001 Spectrum Canter Boulevard
SAN DIEGO CA 92123

Re: K123979
Trade/Device Name: Quattro Air
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 18, 2012
Received: December 26, 2012

Dear Mr. Cassi:

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,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123979

Device Name: **Quattro Air**

Indications For Use:

The Quattro Air Mask System is a non-invasive accessory used for channelling air-flow (with or without supplemental oxygen) to a patient from a positive airway pressure device such as Continuous Positive Airway Pressure (CPAP) or bilevel system.

The Quattro Air Mask System is:

- to be used by patients (weighing >66 lb/30 kg) for whom positive airway pressure therapy has been prescribed.
- intended for single patient re-use in the home environment and multi-patient re-use in the hospital/institutional environment..

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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

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