510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Prepared 15 April 2009

Official Contact Mr. Steven Lubke
Director Regulatory Affairs

Device Trade Name Quattro™ LT

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)
Ultra Mirage II Mask (K050359)

Description The Quattro LT 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 Quattro LT is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.

The Quattro LT is a prescription device supplied non-sterile.

Intended Use The Quattro LT 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 Quattro LT 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

Comparison with predicate Mirage Quattro

The new device and the Mirage Quattro predicate both provide a seal via a silicone interface. Both masks are also 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 the vent-holes does not interfere with the intended performance of the masks.

Both masks contain an antiasphyxia 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 molded plastic and silicone components and fabric / nylon headgear. All components in both 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 devices are substantially equivalent.

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

The main difference between the Quattro LT and the Mirage Quattro is the 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 Full Face 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 Quattro LT, as was the case with the predicate devices.

Performance Data

Comparison with predicate Ultra Mirage II

The CO_2 performance of the new device and the predicate device are substantially equivalent.

Substantial Equivalence Conclusion

Quattro LT 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 Quattro and Ultra Mirage II.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 03 2009

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

Re: K091129
Trade/Device Name: Quattro™ LT
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: June 19, 2009
Received: June 24, 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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division 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: **Quattro™ LT**

Indication for Use

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- to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed
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L Schultz

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

510(k) Number: K091129

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)