510(k) SUMMARY—Hospital Full Face Mask

Submitter Name:	ResMed Ltd
Submitter Address:	97 Waterloo Road, North Ryde NSW 2113, Australia
Contact Person:	David D'Cruz, VP Regulatory & Clinical Affairs US
Phone Number:	(858) 746 2238
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Date Prepared:	May 17, 2004
Device Trade Name:	ResMed Hospital Full Face Mask
Device Common Name/ Classification Name:	Full Face Mask
Predicate Devices:	K023244: Mirage Full Face Mask Series 2
Device Description:	The Hospital Full Face Mask is a respirator mask covering the nose and the mouth. It is a patient interface accessory for use with CPAP and bilevel devices.
Intended Use:	The Hospital Full Face Mask is intended for single patient use for adult patients (>30 Kg) prescribed continuous positive airway pressure or bilevel therapy in hospitals or clinics. This is a disposable mask. It is intended to be used for the short-term (maximum 7 days) treatment of a single patient only, then discarded.

Device Technological Characteristics and Comparison to Predicate Device(s):

The Hospital Full Face Mask is strapped to the patient's face covering the nose and mouth. It is connected via tubing to a CPAP or bilevel flow generator. Positive pressure ventilation is thus applied to the lungs in a non-invasive way.

The Hospital Full Face Mask comes in 3 sizes, small, medium and large. Each size comprises a frame, cushion and cushion clip.

The Hospital Full Face Mask is substantially equivalent to the Mirage Full Face Mask Series 2. The two masks have a substantially equivalent intended use (Hospital Full Face Mask for single patient use only), same operating principle, same technological characteristics and same manufacturing process. The Mirage Full Face Mask is cleared for multi patient multi use. The Hospital Full Face Mask is for single patient multiple use only.

Performance Data:

Testing is provided to demonstrate that the Hospital Full Face mask is substantially equivalent to the Full Face Mask series 2. The original testing that was performed for the Full Face Mask Series 2 was reviewed as an input to the selected test methods. This testing provided represents ResMed's state of the art knowledge and procedures.

Materials Biocompatibility

The materials used for the mask components, which contact the skin and/or the air-path, are either predicate materials (i.e., cleared previously for the same intended use), are in compliance with ISO10993-1 or have been submitted to an independent accredited laboratory for conformance to ISO10993-1. ResMed has procedures in place to ensure that the ISO10993-1 test results are reviewed and accepted prior to implementation and release of the material for use in producing masks products.

Conclusion:

The Hospital Full Face Mask is substantially equivalent to the Mirage Full Face Mask Series 2. The changes in design do not affect safety and effectiveness of the Hospital Full Face Mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2004

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

Re: K041362
Trade/Device Name: ResMed Hospital Full Face Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: May 17, 2004
Received: May 20, 2004

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.

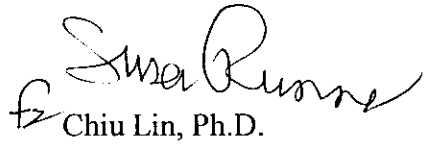
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
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): **K041362**

Device Name: **ResMed Hospital Full Face Mask**

Indications for Use:

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This is a disposable mask. It is intended to be used for the short-term (maximum 7 days) treatment of a single patient only, then discarded.

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)

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

510(k) Number: K041362