3 510(K) SUMMARY

510(k) SUMMARY—Ultra Mirage II Mask

Submitter Name:	ResMed Corp.
Submitter Address:	14040 Danielson Street, Poway CA 92064-6857 USA
Contact Person:	David D'Cruz, VP US Clinical & Regulatory Affairs
Phone Number:	(858) 746 2238
Fax Number:	(858) 746 2915
Date Prepared:	February 11, 2005
Device Trade Name:	Ultra Mirage II Mask
Device Common Name/ Classification Name:	Ultra Mirage II Mask
Predicate Devices:	K961783 Modular Mask K032916 Mirage Activa

Device Description:

The Ultra Mirage II Mask is designed for adult patients for the delivery of non-invasive ventilatory support using continuous positive airway pressure or bi-level therapy. It is intended for multiple-patient re-use and is minimally obtrusive to the user, providing a high level of comfort, ease-of-use and seal.

Intended Use:

The Ultra Mirage II Mask is intended for multipatient re-use for adult patients prescribed continuous positive airway pressure (CPAP) or bilevel therapy in hospitals, clinic and home environments.

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

Overview:
The Ultra Mirage II Mask is a nasal mask supported by headgear to allow a seal with the patients face. The Ultra Mirage II Mask may then be connected via tubing to a CPAP or bi-level flow generator whereby positive pressure ventilation is applied to the lungs in a non-invasive manner.

The Ultra Mirage II Mask comes in one frame size with four cushion variants (standard, large, shallow, shallow-wide).

The Ultra Mirage II Mask design is substantially equivalent to predicate devices. The Ultra Mirage II Mask design has the same intended use and has the same fundamental scientific technology as its predicates.

Performance Data:
Performance testing has been carried out to verify the safety and effectiveness of the Ultra Mirage II Mask. The Ultra Mirage II Mask performance is equivalent to ResMed's Ultra Mirage Mask as reviewed by the FDA as part of the Autoset Spirit (K013843) and S7 Elite (K013909) submissions. The results of the performance data show that the Ultra Mirage II mask is substantially equivalent to the Modular (K961783) and Mirage Activa (K032916) predicate masks (refer section 5.2.1)

Materials Biocompatibility

Materials have been carefully selected to ensure patient safety and efficacy of the product. Those materials used to create components of the Ultra Mirage II Mask, which contact the skin and/or the air-path, have been tested to the ISO 10993 standards by an independent certified laboratory. The details are referenced in section 5.4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2005

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

Re: K050359
Trade/Device Name: Ultra Mirage II Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 11, 2005
Received: February 14, 2005

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 (240) 276-0120. 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/industry/support/index.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

4 INDICATIONS FOR USE

510(k) Number (if known): K050359

Device Name: **Ultra Mirage II Mask**

Indications For Use:

The Ultra Mirage II Mask is intended for multipatient re-use for adult patients prescribed continuous positive airway pressure (CPAP) or bilevel therapy in hospitals, clinic and home environments.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (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)

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices
...) Number: K050359