510(k) SUMMARY—Hospital Nasal Mask

Submitter Name:	ResMed Ltd
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Date Prepared:	March 2, 2004
Device Trade Name:	ResMed Hospital Nasal Mask
Device Common Name/ Classification Name:	Nasal Mask
Predicate Devices:	K961783 Modular Mask – cleared as part of the VPAP II ST system
Device Description:	The Hospital Nasal Mask is a respirator mask covering the nose. It is a patient interface accessory to CPAP and bilevel devices for use in hospitals and clinics.
Intended Use:	The Hospital Nasal Mask is an accessory to a non-continuous ventilator (Respirator) intended for single patient, multi-use for adults prescribed continuous positive airway pressure (CPAP) or Bilevel therapy in hospitals or clinics.

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

The Hospital Nasal Mask is strapped to the patient's face covering the nose. It is connected via tubing to a CPAP or bi-level flow generator. Positive pressure ventilation is thus applied to the lungs in a non-invasive way.
The Hospital Nasal Mask is a single patient multiple-use medical accessory. The mask will be marketed to clinics and hospitals for short-term use.

The Hospital Nasal Mask is a modified version of the Modular Mask (cleared by FDA in K961783). The Hospital Nasal Mask is shown to be substantially equivalent to the Modular Mask. Both masks have the same intended use, operating principle, technological characteristics and a similar manufacturing process. The intended life of the Hospital Nasal Mask is restricted to 7 days to reflect the clinical needs of a hospital and clinic mask.

Risk Analysis and Performance Data:

The risk analysis for the modified device is provided in section 5.2.1. Performance testing derived from the risk analysis is provided (section 5.2.2) in order to demonstrate safety and effectiveness of the Hospital Nasal Mask and ensure that the design input requirements have been met.

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), or are compliant with ISO 10993 standards. Results are provided in section 5.4.

Conclusion:

The results of the performance data and materials biocompatibility testing show that the mask is substantially equivalent with the unmodified predicate mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

Mr. David D' Cruz
Resmed Limited
Vice President Regulatory & Clinical Affairs US
Resmed Corporation
97 Waterloo Road
North Ryde NSW 2113
AUSTRALIA

Re: K040566
Trade/Device Name: Resmed Hospital Nasal Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 2, 2004
Received: March 4, 2004

Dear Mr. 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.

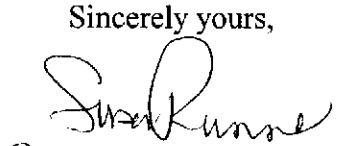
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-5613. 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,



for 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): K040566

Device Name: Hospital Nasal Mask

Indications For Use:

The Hospital Nasal Mask is an accessory to a non-continuous ventilator (Respirator) intended for single patient, multi-use for adults prescribed continuous positive airway pressure (CPAP) or Bilevel therapy in hospitals or clinics.
This is a disposable mask. It is intended to be used for the short-term (7 days) treatment of a single patient only, then discarded.

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)

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

510(k) Number: K040566