K023068

MAY 28 2003

1.2 510(k) SUMMARY of Safety & Effectiveness

1.2.1 General Information

Submitter	MAP Medizin-Technologie GmbH Fraunhoferstrasse 16 82152 Martinsried GERMANY
Contact Person	Torsten Schlichtholz Manager QA and Regulatory Affairs
Date of Submission	06 September 2002
Phone No.	+49 89 89518723
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Classification Reference	21 CFR 868.5905
Product Code	BZD – noncontinuous ventilator
Device Class	Class II
Common/Usual Name	nasal mask
Proprietary Name	Papillon® Mask Set
Predicate Device	Sullivan® Mirage™ Mask System (K984428)
Reason for submission	New Device

1.2.2 Substantial Equivalence

The Papillon® Mask Set is substantially equivalent to the predicate ResMed Sullivan® Mirage™ Mask System. Both masks have the same intended use, environment of use and patient population. Verification testing has been performed and demonstrates that the exhalation vents perform equivalently in preventing CO_2 re-breathing as compared to the predicate mask system. Based on verification testing, we conclude that the differences (e.g. design of mask cushion, mask framè, forehead pads, adaptation to the respiratory hose) do not affect safety and effectiveness of the Papillon® Mask Set.

1.2.3 Intended Use

The Papillon® Mask Set is used to treat patients who require a nasal positive airway pressure therapy (CPAP or bi-level).

1.2.4 Device Description

The Papillon® Mask Set is a patient interface accessory for use with nasal **C**ontinuous **P**ositive **A**irway **P**ressure (CPAP) and bi-level systems used in the treatment of **O**bstructive **S**leep **A**pnea (OSA).

One mask set consists of a mask cushion, forehead pad, mask frame, hose connector system and the AeroFix headgear with the AeroFix plus hose clip. The mask cushion is available in two different sizes.

The mask fame integrates the standard mask frame and the forehead frame into one piece with an adjustable hinge design, which forms the central and supporting part of the Papillon nasal mask. The mask cushion and forehead pad are fixed to the mask frame prior to use. The mask cushion and forehead pad are both made of a hypoallergenic silicone material. The mask cushion and outer shell are comprised of a single, soft, silicone piece that covers the entire nasal area. The cushion includes an exhalation system consisting of six exhalation vents. The hose connection system allows a standard respiratory hose to be connected to the Papillon nasal mask. The hose connection system includes two connectors for external pressure measurement and for administering O_2. The Aerofix headgear and Aerofix plus hose clip are easily connected to the mask frame and the respiratory hose using fasteners. The Aerofix headgear secures the nasal mask to the head of the patient.

The mask was tested and found compliant with ISO 10993-1 "Biological Evaluation of Medical Devices" and with the European Standard prEN ISO 17510-2 "Sleep apnoea breathing therapy – Part 2: Masks and application accessories".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2003

MAP Medizintechnik Für Arzt Und Patient
C/O Mr. Roger Kotter
Resmed Corporation
14040 Danielson Street
Poway, California 92064

Re: K023068
Trade/Device Name: Papillon® Mask Set
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 24, 2003
Received: February 27, 2003

Dear Mr. Kotter:

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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K023068

DEVICE NAME: Papillon® Mask Set

INDICATIONS FOR USE:

The Papillon® Mask Set is intended to be used with positive airway pressure devices such as CPAP (Continuous Positive Airway Pressure), operating at or above 4 cm H_2O for the treatment of adult obstructive sleep apnea. The mask is single patient reusable.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1)

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

510(k) Number: K023068