SECTION 5 – 510K Summary

K063036

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DEC 2 2 2006

Contact person	Jayanti Karandikar
Date prepared	30th September 2006
Trade name	Opus HC482 Direct Nasal Mask
Common name	Direct Nasal Mask
Classification name	Non continuous ventilator IPPB (21 CFR § 868.5905, product code BZD)
Predicate devices	K042403 Resmed Mirage Swift™ K061236 Fisher & Paykel Healthcare Flexifit HC432 Full Face Mask and K050904 HC238 Fisher & Paykel Healthcare Cpap Humidifier (predicates for material biocompatibility)

5.1 Description

The Opus HC482 Direct Nasal Mask is a non invasive patient interface that is ideal for people who want an alternative to a traditional nasal mask. The unique design of the mask and the headgear minimizes facial contact and reduces pressure points.

The HC482 Direct Nasal Mask is a non invasive patient interface, the pillows of which are positioned inside the patient's nostrils. The mask is held on the face with headgear straps. It connects to a single breathing tube via a swivel adaptor, to receive pressurized gases. On the mask base are exhalation vents (bias holes) located on the elbow that allows exhaled gases to be continually flushed and removed to room air. The nasal prongs on the silicone seal are contoured for comfort and to reduce leakage.

5.2 Intended Use

The Opus HC482 Direct Nasal Mask is designed for adult patients requiring CPAP or Bilevel ventilator treatment in the home, hospital or other clinical setting. The mask may be reprocessed and reused by healthcare facilities to allow multi-patient use. The mask may be reprocessed up to 20 times.

5.3 Technological Characteristics Comparison

The HC482 Direct Nasal Mask is very similar to the predicate RESMED Mirage Swift™ Nasal Pillows System. It uses a similar seal, base and headgear system. Both masks are for non continuous ventilation. The HC482 Direct Nasal Mask differs mainly in terms of geometry of individual components and their attachment mechanisms. The major differences are the inability of the prongs of the HC482 to swivel with respect to the headgear, the positioning of the hose, and the location, size and number of bias holes.

5.4 Non-clinical Tests

Testing of the Opus HC482 Direct Nasal Mask was compared to the predicate RESMED Mirage Swift™ for performance and biocompatibility. These tests demonstrate substantial equivalence of the Opus HC482 Direct Nasal Mask to the predicate mask. Copies of test reports are included in Appendix B.

5.5 Conclusion

The comparison of features, performance, and intended use demonstrate that the Infinity HC482 Direct Nasal Mask is substantially equivalent to the predicate RESMED Mirage Swift™. The Opus HC482 Direct Nasal Mask is proven to be safe and effective for CPAP and Bilevel ventilation therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Ms. Jayanti Karandikar
Regulatory Affairs Engineer
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Re: K063036
Trade/Device Name: Opus HC482 Direct Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 30, 2006
Received: October 3, 2006

Dear Ms. Karandikar:

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

SECTION 4 – Indications for Use Statement

510(k) Number

Device Name Opus HC482 Direct Nasal Mask

Indications for Use:

The Opus HC482 Direct Nasal Mask is intended for multiple patient or single patient adult use by individuals who have been diagnosed by a physician as requiring CPAP or Bilevel ventilator treatment in the home, hospital or other clinical setting.

Prescription Use ____✓____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila R Murphy MD 12/26/06

Physiology, General Hospital
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