JAN 14 2005

K042455

## 16.0 510(k) Summary

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| **Submitter's Name:** | Sunrise Medical HHG, Inc.<br>Respiratory Products Division<br>100 DeVilbiss Drive<br>Somerset PA 15501 |
| **Contact Person:** | Allan Jones<br>Phone: 814-443-7618<br>Fax: 814-443-7571<br>Email: allan.jones@sunmed.com |
| **Date Prepared:** | September 1, 2004 |
| **Device Name:** | Nasal CPAP Mask |
| **Common or Usual Name:** | Nasal CPAP Mask |
| **DeVilbiss Model Number:** | Model 9354 Series |
| **Trade Proprietary Name:** | DeVilbiss Nasal CPAP Mask |
| **Established Registration Number:** | 2515872 |
| **Classification Panel:** | Anesthesiology |
| **FDA Classification:** | Class II |
| **CFR Section:** | 868.5905 – Noncontinuous Ventilator (IPPB) |
| **Product Code:** | BZD |

**Legally Marketed Predicate Devices:**

| Device Name | 510(k) Notification |
|---|---|
| Respironics Gel Mask | K954207 |
| Invacare Twilight Nasal Mask | K022642 |

**Description of Device:**

The new DeVilbiss Nasal CPAP Mask serves as a mechanism for reliably connecting an adult (>30kg) patient diagnosed with sleep apnea to a source of continuous or bilevel positive air pressure needed to maintain an open airway. The nasal mask is securely fastened over a patient's nose by use of specialized headgear. A soft contact area is provided on the side of the mask that contacts the patient's face; the front side of the mask assembly has a tubing connection which is compatible with the industry standard 22mm air tubing.

The CPAP mask is required to be secure fitting to insure proper pressure delivery to the patient, but comfortable enough to maintain patient compliance with the treatment.

Air is supplied to the mask by a CPAP device (the CPAP device can be a standard CPAP, AutoAdjust CPAP or Bi-Level type device). Air is channeled to the nose chamber via the tubing/swivel adapter connections. The patient inhales air from the mask and exhales into the mask where continuous airflow from the CPAP device purges the exhaled carbon dioxide from the mask through the mask diffusion based exhaust holes. The mask will be held in place on the patient through the use of a cloth/elastic headgear.

**Statement of Intended Use:**

The new Nasal CPAP Mask is intended to be used with nasal continuous positive airway pressure (CPAP), auto-adjusting CPAP and Bilevel systems for the treatment of adult (>30kg) Obstructive Sleep Apnea (OSA). The device is to be used in home and clinical environments by or on order of a physician. The device can be used with auto-adjusting PAP devices which depend on patient flow signals or flow-based snoring signals for the determination of pressure adjustment.

**Statement of Safety and Effectiveness:**

The new Nasal CPAP Mask is equivalent in both function and indications for use to the Respironics Gel Mask (K954207) and Invacare Twilight Nasal Mask (K022642) legally marketed predicate devices.

The new Nasal CPAP Mask is designed for use on the order of a physician for the treatment of adult (>30kg) Obstructive Sleep Apnea. The mask is constructed of materials that are similar or identical to legally marketed devices. The unit is designed and manufactured to comply with voluntary standards applicable to this type of device.

The new Nasal CPAP Mask is designed to serve as a mechanism for reliably connecting an adult (>30kg) patient to a source of continuous or bilevel positive air pressure needed to maintain an open airway. The method of serving as the mechanism of connection to a continuous or Bilevel positive air pressure and other characteristics of the new Nasal CPAP Mask are substantially equivalent to other legally marketed devices.

**Technological Characteristics:**

The new Nasal CPAP Mask is strapped to the patient's face covering the nose, and connected via 22mm tubing to a source of continuous or Bilevel positive air pressure, creating an airway splint in the throat. Positive pressure ventilation is thus applied to the lungs in a non-invasavive way. The new Nasal CPAP Mask is equivalent in functional characteristics to the existing legally marketed predicate devices. The devices all function in providing a reliable mechanism of connection to a continuous, auto adjust or Bilevel positive air pressure source for the treatment of Obstructive Sleep Apnea. No new technologies have been introduced in the new Nasal CPAP Mask device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2005

Mr. Allan Jones
Manager, Sleep Products Engineering
Sunrise Medical
100 DeVilbiss Drive
Somerset, Pennsylvania 15501-2125

Re: K042455
Trade/Device Name: DeVilbiss Nasal CPAP Mask, Model 9354 Series
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: November 24, 2004
Received: November 29, 2004

Dear Mr. Jones:

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/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): K042455

Device Name: DeVilbiss 9354 Series Nasal CPAP Mask

Indications For Use:

The new Nasal CPAP Mask is intended to be used with nasal continuous positive airway pressure (CPAP), auto-adjusting CPAP and Bilevel systems for the treatment of adult (> 30Kg) Obstructive Sleep Apnea (OSA). The device is to be used in home and clinical environments by or on order of a physician. The device can be used with auto-adjusting PAP devices which depend on patient flow signals or flow-based snoring signals for the determination of pressure adjustment.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K042455