K061099

AUG 11 2006

Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

Company Name: Hoffman Laboratories, LLC
9305 Eton Ave
Chatsworth CA 91311

Contact: Keith Bosecker, President

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Summary Date: April 14, 2006

Trade Name: Hoffman Laboratories BreatheX™ Nasal Interface System

Common Name: CPAP Device Accessory

Common Classification/Name: Ventilator, non-continuous, non-life supporting

Product Code(s): 21 CFR 868.5905 BZD

Class: Class II

Predicate Devices:

- **510K Number:** K031883
- **Manufacturer:** SensorMedics Corporation (VIASYS)
- **Trade Name:** Lyra Nasal Interface

- **510K Number:** K050359
- **Manufacturer:** ResMed Limited
- **Trade Name:** Ultra Mirage II Mask

Reason for Submission: New Device

Description of Device

The BreatheX Nasal Interface System has been designed for use as an accessory with commonly marketed CPAP units. The device consists of a plastic manifold with integral exhaust port, nasal mask cushion, a set of nasal pillows, adjustable headgear straps, and an interface tube with a 22mm fitting.

The Nasal Interface System allows a patient to use either the nasal pillows or nasal mask cushion interchangeably. The lightweight construction of the device is designed to maximize patient comfort.

The device is labeled for single patient use.

Intended Use

The BreatheX Nasal Interface System is intended for use as accessory device to CPAP machines in the treatment of obstructive sleep apnea (OSA).

The BreatheX Nasal Interface System is for use on adult spontaneously breathing (non-ventilator dependant) patients at home or in the sleep clinic.

Indications for Use

The BreatheX Nasal Interface System is an accessory intended for use with devices that deliver Continuous Positive Airway Pressure (CPAP) and bi-level positive airway pressure in treating adult patients.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Technology

The BreatheX Nasal Interface device utilizes similar technological characteristics as the predicate devices. All devices utilize a rigid plastic manifold with a soft silicone rubber seal to the area around the nose or the nasal passages. All devices are attached to the patient's head using flexible adjustable straps.

Like the predicate devices, the manifold of the BreatheX Nasal Interface System has an integral exhaust port which continuously vents a portion of the CPAP treatment air in order to minimize the rebreathing of expired gases.

Non-Clinical Tests Submitted:

The device was tested in accordance with applicable standards for medical device environmental temperature and humidity, shock and vibration, and moisture ingress. The BreatheX Nasal Interface System passed all of the tests.

Static and dynamic performance testing was conducted in comparison with the predicate devices for dead space, pressure-flow characteristics and sound output level. The device met specified requirements and was comparable to the applicable specifications of the predicate devices.

The materials utilized in the device comply with biocompatibility requirements appropriate for the intended use.

Risk and Hazard analyses were performed, and the results of the analyses demonstrated that the residual risks were acceptable for the intended use.

Clinical Tests Submitted: None

Conclusions

The function of the BreatheX Nasal Interface System is substantially equivalent to the predicate devices. Laboratory and standards compliance tests are provided to support the safety and performance of the device.

As described above, all of the testing demonstrates that the Hoffman Laboratories BreatheX Nasal Interface System is as safe and effective and performs in a manner equivalent to the predicate nasal interface devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

Mr. Keith Bosecker
President
Hoffman Laboratories, LLC
9305 Eton Avenue
Chatsworth, California 91311

Re: K061099
Trade/Device Name: Hoffman Laboratories BreatheX™ Nasal Interface System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: August 3, 2006
Received: August 7, 2006

Dear Mr. Bosecker:

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.

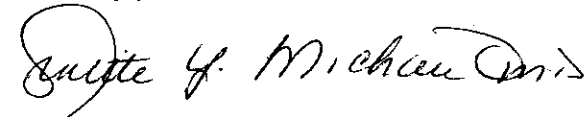
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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

Indications for Use

510(k) Number (if known):

Device Name: Hoffman Laboratories BreatheX™ Nasal Interface System

Indications for use:

The BreatheX Nasal Interface System is an accessory intended for use with devices that deliver Continuous Positive Airway Pressure (CPAP) and bi-level positive airway pressure in treating adult patients.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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

[signature]
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(510(k) Number K061099