DEC 16 2005

K052597

Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

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

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Summary Date: November 30, 2005

Trade Name: BreatheX™ Omega™ CPAP Device

Common Name: CPAP Device

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

Product Code(s): 21 CFR 868.5905 BZD

Class: Class II

Predicate Device(s):

- **510K Number:** K973161
- **Manufacturer:** Fisher & Paykel Healthcare
- **Trade Name:** HC200 CPAP

- **510K Number:** K990871
- **Manufacturer:** LifeSleep Systems, Inc.
- **Trade Name:** PillowPositive Cervical Pillow

Reason for Submission: New Device

Description of Device

The BreatheX provides a continuous positive airway pressure (CPAP) to support treatment of obstructive sleep apnea. The device is battery operated.

The BreatheX Omega is comprised of a motorized blower assembly that provides positive air pressure. The blower speed is directly related to air pressure, and is controlled by software.
The BreatheX Omega CPAP device consists of the following main components:

- CPAP blower
- Battery/Battery charger
- Therapy Tubing

The patient interface (CPAP mask) is a commercially available accessory provided separately. The patient interface is not covered in this submission.

Intended Use

The BreatheX Omega continuous positive airway pressure (CPAP) device is intended for use in the treatment of obstructive sleep apnea (OSA).

The BreatheX Omega CPAP is used while sleeping, for the purpose of treating Obstructive Sleep Apnea (OSA). This is by the delivery of Continuous Positive Airway Pressure (CPAP) at a specified pressure level in order to prevent airway obstruction.

The BreatheX Omega CPAP is for use on adult patients weighing at least 30 kg, spontaneously breathing (non-ventilator dependant) patients at home or in the sleep clinic.

The BreatheX Omega is not intended for life support.

Indications for Use

The BreatheX Omega CPAP device is intended for treatment of obstructive sleep apnea (OSA) in spontaneously breathing adults weighing at least 30 kg.

The BreatheX Omega CPAP device provides continuous positive airway pressure.

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

Technology

The BreatheX Omega CPAP device utilizes similar technological characteristics as the predicate CPAP device. Both devices employ a computer controlled

blower system which is attached via tubing to a nasal mask/exhaust port to deliver a specified mono-level CPAP treatment to a patient.

The BreatheX Omega utilizes a battery for the power source. The device does not provide integrated humidification.

Non-Clinical Tests Submitted:

The device was tested in accordance with applicable standards for medical device Electrical Safety, Electromagnetic Compatibility, Shock and Vibration, and Environmental Temperature and Humidity. The BreatheX Omega CPAP device passed all of the tests.

Static and dynamic pressure testing was performed in comparison with the predicate device. The device met specified requirements and was comparable to the applicable specifications of the predicate device.

Embedded software in the device was verified to requirements and validated to meet intended use by software and system level performance testing.

Clinical Tests Submitted: None

Conclusions

The function of the BreatheX Omega CPAP device is substantially equivalent to the predicate device(s). Laboratory, software, and standards compliance tests are provided to support the safety and performance of the BreatheX Omega.

As described above, all of the testing demonstrates that the Hoffman Laboratories BreatheX Omega CPAP device is as safe and effective and performs in a manner equivalent to the predicate device, the Fisher and Paykel HC200.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

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

Re: K052597
Trade/Device Name: Hoffman Laboratories BreatheX Omega CPAP Device
Regulation Number: 868.5905
Regulation Name: Noncontinuous ventilator (IPPB
Regulatory Class: II
Product Code: BZD
Dated: December 1, 2005
Received: December 5, 2005

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) 276-0120. 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

Indications for Use

510(k) Number (if known):

Device Name: Hoffman Laboratories BreatheX™ Omega™ CPAP Device

Indications for use:

The BreatheX Omega CPAP device is intended for treatment of obstructive sleep apnea (OSA) in spontaneously breathing adults weighing at least 30 kg.

The BreatheX Omega CPAP device provides continuous positive airway pressure.

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)

[illegible] General Hospital,
[illegible] Devices

[illegible] Number: K052597