

JUN 1 2 2007

K071069

Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

Company Name: VIASYS Sleep Systems LLC
9305 Eton Ave
Chatsworth CA 91311

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Summary Date: April 12, 2007

Trade Name: Mini CPAP and Humidifier Accessory

Common Name: CPAP and Humidifier Device

Common Classification/Name: Ventilator, non-continuous, non-life supporting;
Humidifier, respiratory gas

Product Code(s): 21 CFR 868.5905 73 BZD & 21 CFR 868.5450 73 BTT

Class: Class II

Predicate Device(s):

- **Predicate Device:** BreatheX Omega CPAP Device, Model 322
- **510K Number:** K052597
- **Manufacturer:** Hoffman Laboratories (now VIASYS Sleep Systems)

- **Predicate Device:** HC200 CPAP
- **510K Number:** K973161
- **Manufacturer:** Fisher & Paykel Healthcare

Reason for Submission: New Device

Description of Device

The Mini CPAP and Humidifier Accessory provide a continuous positive airway pressure (CPAP) to support treatment of obstructive sleep apnea. The Mini CPAP device can be operated from mains supply or an optional battery.

The Mini CPAP 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 Mini CPAP and Humidifier Accessory consist of the following main components:

- CPAP blower
- Humidifier
- Power Supply
- Therapy Tubing
- Optional Battery and Charger

The Humidifier accessory is designed for operation only with the Mini CPAP device and utilizes a temperature controlled heated water tray and a manifold to provide humidified air to the patient. The humidification level is user adjustable. Moisture contacting materials in the humidifier and therapy tube meet biocompatibility requirements.

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

Intended Use

The Mini CPAP provides continuous positive airway pressure (CPAP) intended for use in the treatment of obstructive sleep apnea (OSA). This is by the delivery of continuous positive airway pressure at a specified pressure level in order to prevent airway obstruction.

The Mini CPAP and Humidifier Accessory are used while sleeping, for the purpose of treating Obstructive Sleep Apnea (OSA). The Humidifier Accessory provides humidification of the air delivered to the patient.

The Mini CPAP and Humidifier Accessory are for use on adult patients weighing at least 30 kg, spontaneously breathing (non-ventilator dependent) patients at home or in the sleep clinic.

The Mini CPAP and Humidifier are not intended for life support.

Indications for Use

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

The VIASYS Sleep Systems Mini CPAP device provides continuous positive airway pressure.

The Humidifier accessory provides humidification of the air delivered to the patient.

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

Technology

The Mini CPAP device utilizes similar technological characteristics as the predicate CPAP devices. All 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 humidifier in the Mini CPAP has the same operating principles, a heated water container, as the predicate device.

The Mini CPAP operates from a mains powered 12 V power supply or an optional battery. The Humidification accessory utilizes a mains powered 12 V power supply only.

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 Mini CPAP and Humidifier Accessory passed all of the tests.

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

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 Mini CPAP and Humidifier Accessory device is substantially equivalent to the predicate devices. Laboratory, software, and standards compliance tests are provided to support the safety and performance of the Mini CPAP and Humidifier Accessory.

As described above, all of the testing demonstrates that the VIASYS Sleep Systems LLC Mini CPAP and Humidifier Accessory is as safe and effective and performs in a manner equivalent to the predicate devices, the Fisher and Paykel HC200 and Hoffman Laboratories (now VIASYS Sleep Systems) BreatheX Omega CPAP Device, Model 322.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Keith Bosecker
Regulatory Affairs
VIASYS Sleep Systems, LLC
9305 Eton Avenue
Chatsworth, California 91311

JUN 12 2007

Re: K071069
Trade/Device Name: VIASYS Sleep Systems Mini CPAP Device with Humidification
Accessory
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilators (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 15, 2007
Received: April 16, 2007

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.

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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

Indications for Use

510(k) Number (if known):

Device Name: VIASYS Sleep Systems Mini CPAP Device with Humidification Accessory

Indications for use:

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

The VIASYS Sleep Systems Mini CPAP device provides continuous positive airway pressure.

The Humidifier accessory provides humidification of the air delivered to the patient.

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND / OR

Over-The-Counter Use _____
(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)



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

510(k) Number: K 071069