AEIOMed

MAR 3 - 2005

K042945

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Minneapolis, MN 55414
Ph: 612-455-0550
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Summary of Safety and Effectiveness

Company Name: AEIOMed, Inc.
1313 5th Street SE, Suite 205
Minneapolis, MN 55414

Contact: Dave Markovich, Senior Director of Operations

Phone: (612) 455-0550

Fax: (612) 455-0551

Summary Date: January 26, 2005

Trade Name: aura CPAP System

Common Name: CPAP Device

Classification Name: 21 CFR 868.5905, Non-Continuous (Respirator) Ventilator

Predicate Devices:

510(k) Number: K030985
Manufacture: Vital Signs, Inc.
Trade Name: BREAS PV10 CPAP System

510(k) Number: K010263
Manufacture: Respironics, Inc.
Trade Name: REMstar Plus CPAP System

1.0 Description of Device

The aura CPAP System provides a continuous positive airway pressure (CPAP) to support treatment of obstructive sleep apnea. During obstructive sleep apnea, the airway collapses. When interfaced with a CPAP Mask or CPAP Patient Interface the aura CPAP System provides a constant pressure of 4 to 20 cmH_2O above the ambient atmospheric pressure to patient's nasal airway. This constant pressure supports retaining an open airway during sleep.

The aura CPAP System is initially used under the direct supervision of a trained medical professional. The aura CPAP System function and applications may be reviewed in a clinical setting when the patient is treated for obstructive sleep apnea by the application of CPAP therapy.

2.0 Intended Use

The aura CPAP System provides continuous positive airway pressure (CPAP) to support treatment of adults (over 30kg) with Obstructive Sleep Apnea.

3.0 Technology

The aura CPAP System has four significant components:

1) CPAP Blower,
2) Optional Humidifier,
3) Optional Battery Pack, and
4) Patient Interface.

The Patient Interface or CPAP Mask is a commercially available accessory provided to the user separately. The Patient Interface or CPAP Mask is not addressed in this submission.

4.0 Conclusions

The aura CPAP System is substantially equivalent to the predicate devices. Laboratory and standards compliance were provided to support the aura CPAP System performance. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 - 2005

AEIOMed, Incorporated
C/O Mr. Gary Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K042945
Trade/Device Name: CPAP System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: January 28, 2005
Received: January 31, 2005

Dear Mr. Syring:

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

Indications for Use

510(k) Number (if known): K042945

Device Name: aura CPAP System

Indications for Use:

The aura CPAP System provides continuous positive airway pressure (CPAP) to support treatment of adults (over 30kg) with Obstructive Sleep Apnea.

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)

[signature]

[illegible] General Hospital,
[illegible] Devices

[illegible] Number K042945