K100121

JUL 13 2010

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Minneapolis, MN 55414
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510(k) Summary

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

Contact: Bruce Bowman, CTO

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Summary Date: May xx, 2010

Trade Name: Model 300157 CPAP System

Common Name: CPAP Device

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

Predicate Devices:

510(k) Number: K042945
Manufacture: AEIOMed, Inc
Trade Name: Aura

510(k) Number: K042130
Manufacture: AEIOMed, Inc
Trade Name: Aura Interface

510(k) Number: K052597
Manufacture: Hoffman
Trade Name: BreatheX

1.0 Description of Device

The 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 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, when set to a therapeutic level as prescribed by a physician, supports retaining an open airway during sleep.

The CPAP System is initially used under the direct supervision of a trained medical professional. The 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 Model 300157 CPAP System is a single patient reusable device. The Model 300157 CPAP System provides continuous positive airway pressure (CPAP) to support treatment of adults (over 30 kg) with Obstructive Sleep Apnea.

3.0 Technology

The CPAP System has primary components:

1) CPAP main unit,
2) Removable headgear,
3) External power supply/optional mobile power adaptor, and
4) Patient Interface.

4.0 Conclusions

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Bruce Bowman
Chief Technology Officer
AEIOMed, Incorporated
1313 5th Street SE, Suite 205
Minneapolis, Minnesota 55414

JUL 13 2010

Re: K100121
Trade/Device Name: Model 300157 CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: June 2, 2010
Received: June 16, 2010

Dear Mr. Bowman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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 Form

Indications for Use

510(k) Number (if known): K100121

Device Name: Model 300157 CPAP System

Indications for Use:

The Model 300157 CPAP System is a single patient reusable device. The Model 300157 CPAP System provides continuous positive airway pressure (CPAP) to support treatment of adults (over 30 kg) 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) 12/13/10

(Division Sign-Off)

Division of Anesthesiology General Hospital

Infection Control, Dental Devices

510(k) Number K100121