**510(k) Summary**
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K100343

Pur-Sleep, Inc.
PO Box 95245
South Jordan, UT 84095

Tel (O) 801-916-2864

APR 23 2010

**Official Contact:** Bret Randall - Owner

**Proprietary or Trade Name:** PAP-Cap™

**Common/Usual Name:** Headgear

**Classification Name/Code:** BZD – ventilator, non-continuous (IPPB)
CFR 868.5905

**Device:** PAP-Cap™

**Predicate Devices:** Suiter – Slumbergear™ headgear – K042294

**Device Description:**
The Pur-Sleep PAP-Cap™ is a simple alternative headgear (with an integrated but fully detachable chin strap) designed to be used with standard patient interfaces, i.e., full face mask, nasal mask and nasal pillow and cannula devices. It is designed to be adjusted to optimize fit and patient comfort. It is adaptable to many models of CPAP mask styles.

**Indications for Use:**
PAP-Cap™ headgear is an accessory intended for patients using CPAP or bi-level devices in hospitals, institutions, sleep labs, and /or home environments. The headgear is single patient, multi-use.

**Environment of Use:**
Hospital, institutions, sleep labs, and home environments

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**Summary of substantial equivalence**

| | **Proposed Pur-Sleep PAP-Cap™ headgear** | **Predicate K042294 Suiter Slumbergear™ headgear** |
|---|---|---|
| Indications for Use | PAP-Cap™ headgear is an accessory intended for patients using CPAP or bi-level devices in hospitals, institutions, sleep labs, and /or home environments. The headgear is single patient, multi-use. | Slumbergear™ headgear is an accessory to a non-continuous ventilator (respirator), intended for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy in hospital, clinics, and / or home environments. The headgear is reusable and for single use. |
| Environment of use | Hospital, institutions, sleep labs and home use | Hospital, clinics and home use |
| Patient Population | Same patient population as the equipment to which it is attached | Adults |
| Prescriptive | Yes | Yes |
| Patient interface types | Full face mask<br>Nasal mask<br>Nasal pillows<br>Cannulas | Mask<br><br>Nasal pillows<br>Cannulas |
| Design features | One-piece<br>Integrated chinstrap<br>Velcro® attachment means<br>Emergency exit method | One-piece<br>Integrated chinstrap<br>Velcro® attachment means<br>Emergency exit method |
| Latex Free | Yes | Yes |
| Single patient, multi-use | Yes | Yes |
| Cleaning method | Standard washer or<br>Hand wash warm water and soap, air dry | Hand wash warm water and soap, air dry |

It is our view that there are no differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

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

Pur-Sleep, Incorporated
C/O Mr. Paul Dryden
President
Promedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

APR 23 2010

Re: K100343
Trade/Device Name: PAP-CAP™
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 3, 2010
Received: February 5, 2010

Dear Mr. Paul Dryden:

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 General Hospital,
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement



**510(k) Number:** K100343 (To be assigned)

**Device Name:** PAP-Cap™

**Indications for Use:**

PAP-Cap™ headgear is an accessory intended for patients using CPAP or bi-level devices in hospitals, institutions, sleep labs, and /or home environments. The headgear is single patient, multi-use.

**Prescription Use XX** (Part 21 CFR 801 Subpart D) **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)

L Schultheis

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

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