K082237

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510(k) SUMMARY

PURITAN BENNETT
Sandman Duo and Sandman Duo ST

Submitter Information

Mallinckrodt Développement France
10, allée Pelletier Doisy
54601 Villers-lès-Nancy
France

Submitter's Name	Jean-Paul Arnould EMEA RA Manager France
Telephone	+33 383.44.85.00
Fax	+33 383.44.85.01

Submission Correspondent	Tina Dreiling Regulatory Affairs Associate II Covidien, formerly Nellcor Puritan Bennett Inc 6135 Gunbarrel Ave Boulder, CO 80301
Telephone	303-305-2512
Fax	303-305-2212

Device Name

Proprietary Name	Puritan Bennett, Sandman Duo and Sandman Duo ST
Common Name	CPAP device
Classification Name	Non continuous Ventilator (73 BZD), per 21 CFR 868.5905

Device Information

The Sandman Duo and Sandman Duo ST are designed to deliver Continuous Positive Airway Pressure to patients suffering from obstructive sleep apnea. They may be configured with optional humidification.

Predicate Device Equivalence

The Sandman Duo and the Sandman Duo ST are equivalent to the Puritan Bennett Sandman Intro (K071575) for all aspects except the Bilevel mode, to the Puritan Bennett Sandman Info (K080439) only for detection of apneas and hypopneas, the Puritan Bennett GoodKnight 425 (K041819) for the Bilevel mode. The Sandman Duo ST is equivalent to the Puritan Bennett GoodKnight 425 ST (K050072) for the Bilevel mode including optional backup frequency.

The Sandman Duo and Sandman Duo ST, like the predicate devices, are intended to provide Continuous Positive Airway Pressure (CPAP) between 3 and 20 cmH_2O with a Bilevel mode from 3 to 25 cm H_2O to spontaneously breathing patients over 30 Kg for the treatment of Obstructive Sleep Apnea in a hospital and homecare environment, with optional humidification of the delivered air.

Testing was performed to demonstrate that the performance of the Sandman Duo and Sandman Duo ST is equivalent to the legally marketed predicate devices. The safety and effectiveness of the Sandman Duo and Sandman Duo ST were verified through performance related testing that consisted of Electrical Safety, Electromagnetic Compatibility, Mechanical and Environmental Testing. The Sandman Duo and Sandman Duo ST had been found compliant and had been certified to the standards referenced in the "FDA Reviewer Guidance for Premarket Notifications".

Device Description

The Sandman Duo and Sandman Duo ST are designed to deliver Continuous Positive Airway Pressure between 3 and 20 cmH_2O, and may come in different configurations including an optional integrated pass-over or heated humidifier.

The Sandman Duo and Sandman Duo ST are designed to deliver two levels of pressure in Bilevel mode. The positive inspiratory pressure (IPAP) is delivered during the inspiratory phase and can be set up to 25 cm H_2O. The positive expiratory pressure (EPAP) is delivered during the expiratory phase and can be set to 20 cm H_2O.

The Sandman Duo and Sandman Duo ST can be powered either by AC mains (100 VAC to 240 VAC nominal) or by an external 12 VDC battery. The blower motor nominal voltage is 13 VDC. The Sandman Duo and Sandman Duo ST are double-insulated so that grounding is not required.

The Sandman Duo and Sandman Duo ST are for use by prescription only and displays the appropriate labeling.

The Sandman Duo and Sandman Duo ST are configured for patient use by a homecare dealer according to the prescription using the Clinician Manual provided. The devices are operated according to the instructions contained in the Patient Manual.

The Sandman Duo and Sandman Duo ST do not contain any drugs or biological products as components. However, the devices can be used to provide the patient with supplemental oxygen.
The device and accessories are not supplied sterile, nor are they intended to be sterilized.

The Sandman Duo and Sandman Duo ST are for multiple use.
The Sandman Duo and Sandman Duo ST contain no patient contact components.
The Sandman Duo and Sandman Duo ST tubing is equivalent to that of the CPAP predicate devices.
The Sandman Duo and Sandman Duo ST and the air filter are for multiple use. Accessories such as the patient circuit and nasal masks are for single patient use.

The Sandman Duo and Sandman Duo ST rely on 1 microprocessor for setting and viewing various control parameters and turning features on and off, and for controlling the heated humidification.

Pressure delivery for The Sandman Duo and Sandman Duo ST is regulated by a pressure sensor which monitors both ambient and output pressure and provides feedback to the control system.

The Sandman Duo and Sandman Duo ST use software to set the various device parameters such as the prescription pressure and the ramp starting pressure, and to provide heated humidification.

The Sandman Duo and Sandman Duo ST comply with certain voluntary standards, specifically the draft ARDB Reviewer Guidance for Premarket Notification Submissions (Nov 1993) and IEC60601-1.

The Sandman Duo and Sandman Duo ST are not part of a kit.

Indication for Use

The Sandman Duo and Sandman Duo ST are indicated for the treatment of obstructive sleep apnea in spontaneously breathing patients weighing more than 30kg (66lb) within homecare and hospital environments.

Conditions of use

The Sandman Duo and Sandman Duo ST are designed for use at home or in sleep centers. These devices are portable and can be powered from both household and automobile power sources.
The Sandman Duo and Sandman Duo ST may come with an integrated heated humidifier, which is designed to heat and raise the humidity of the air delivered to the patient. When the device is battery-powered, the heated humidification feature cannot be used, but pass-over humidification is still possible. The water chamber is designed to be filled with water only.
If Sandman Duo and Sandman Duo ST do not come with an integrated heated humidifier, pass-over humidification may be achieved by using a water chamber.

Contraindications

There are no contraindications.

Summary of Performance Testing

1. Functional testing confirms that the Sandman Duo and Sandman Duo ST are capable of meeting its stated performance specifications. The device passed all tests.
2. Testing confirms that the Sandman Duo and Sandman Duo ST comply with the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" published by the Division of Cardiovascular, Respiratory, and Neurological Devices. The device passed all tests.
3. All software is tested in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 2005. The devices passed all tests.

Conclusions

We conclude that the Sandman Duo and Sandman Duo ST meet the stated performance specifications and criteria referenced above and that the device and its accessories will operate safely in its intended environment and will be effective in fulfilling the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mallinckrodt Développement France
C/O Ms. Tina Dreiling
Regulatory Affairs Associate II
Covidien
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K082237
Trade/Device Name: Puritan Bennett, Sandman Duo and Sandman Duo ST
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 9, 2008
Received: September 10, 2008

Dear Ms. Dreiling:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin, M.D. for

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:

Device Name: Puritan Bennett, Sandman Duo and Sandman Duo ST

Indications for Use:
The Sandman Duo and Sandman Duo ST are indicated for the treatment of obstructive sleep apnea in spontaneously breathing patients weighing more than 30kg (66lb) within homecare and hospital environments.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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