JUL 2 2 2004

K041819

510(k) SUMMARY

PURITAN BENNETT
GoodKnight 425

1.0 - Submitter Information

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

Submitter's Name : Moustafa Anki
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Preparation Date : June 2004

2.0 - Device Name

Proprietary Name : GoodKnight 425
Common Name : Bi-level CPAP System
Device Classification Name : Noncontinuous Ventilator (73 BZD), per 21 CFR 868.5905

3.0 - Predicate Device Equivalence

We are claiming substantial equivalence to the Puritan Bennett GoodKnight 420S CPAP system, cleared for commercial distribution as per K020886.

4.0 - Device Description

The GoodKnight 425 is designed to deliver Positive Airway Pressure between 3 and 20 cmH_2O in CPAP mode or between 3 and 25 cmH_2O in bi-level mode (EPAP maximum 20 cmH_2O).

The GoodKnight 425 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 GoodKnight 425 is double-insulated so that grounding is not required.

The GoodKnight 425 is set up for use by the homecare dealer using the Clinician Manual provided. The devices are operated according to the instructions contained in the Patient Manual.

The GoodKnight 425 rely on a microprocessor for setting and viewing various control parameters and turning features on and off. The microprocessor is also required for the treatment of various signals from the devices including signals relating to patient cycle detection.

Pressure delivery for the GoodKnight 425 is regulated by a pressure sensor which monitors both ambient and output pressure and provides feedback to the control system.

The GoodKnight 425 uses the same pass over humidifier and interfaces as those approved for use with the GoodKnight 420S. The GoodKnight 425 tubing is equivalent to that of the GoodKnight 420S.

The GoodKnight 425 can also be connected to a computer via an RS232 serial port. The device can be configured from the computer using the SilverLining™ software which is required for downloading and displaying compliance data stored in the device memory.

The GoodKnight 425 is not for use in life-supporting or life-sustaining situations. The devices and/or their accessories are not intended for sterile use.

The GoodKnight 425 is for multiple use. Accessories such as the patient circuit and nasal masks are for single patient use.

The GoodKnight 425 is for use by prescription only and display the appropriate labeling.

The GoodKnight 425 is for use in a hospital and homecare environment.

The GoodKnight 425 does not contain any drugs or biological products as components. However, the devices can be used to provide the patient with supplemental oxygen.

The GoodKnight 425 is not part of a kit.

The GoodKnight 425 uses software to set the various device parameters such as the prescription pressure and the ramp starting pressure.

The GoodKnight 425 complies with the draft ARDB Reviewer Guidance for Premarket Notification Submissions (Nov 1993), IEC 60601-1 and EN ISO 17510-1.

The following functions are available on the GoodKnight 425:

Bi-level Mode

- On/Off
- Set IPAP pressure
- Set EPAP pressure
- Set inspiratory sensitivity
- Set expiratory sensitivity
- Set rise time between EPAP and IPAP
- Set ramp time

C-PAP Mode

- On/Off
- Set Prescription Pressure
- Set Ramp Time
- Set Ramp Starting Pressure
  (available only if Ramp Time is not set to 0)
- View Hour Meter
- View Compliance Meter
- View Embedded Software Version

- Set Ramp Starting Pressure
  (available only if Ramp Time is not set to 0)
- View Hour Meter
- View Compliance Meter
- View Embedded Software Version

5.0 - Intended Use

The Puritan Bennett GoodKnight 425 is intended for use in treating obstructive sleep apnea (OSA) in spontaneously breathing patients weighing over 30 kg within a homecare and hospital environment.

6.0 - Comparison of Technological Characteristics

Both the GoodKnight 420S and GoodKnight 425 are CPAP devices which deliver a constant positive air pressure to the patient at a level prescribed by the practitioner between 4 to 20 cmH_2O (or 25 cmH_2O for IPAP in bi-level mode). However, the GoodKnight 425 can also operate in bi-level mode.

The global architecture of the GoodKnight 420S and the GoodKnight 425 is similar. The voltage range for the GoodKnight 425 is 100 VAC to 240 VAC or 12 VDC as for the GoodKnight 420S. The motor voltage of the GoodKnight 425 is 13 VDC as is the GoodKnight 420S device. The GoodKnight 420S and the GoodKnight 425 are all double-insulated.

As with the GoodKnight 420S, the GoodKnight 425 uses a microprocessor to set the various controls. In common with the GoodKnight 420S, the GoodKnight 425 has got a ramp function which, when activated, progressively attains the set reference pressure within a designated time between 0 to 30 minutes.

The user interface of the GoodKnight 420S and the GoodKnight 425 is similar. Both devices use an LCD screen with a four button keypad to access and view various device settings. Available settings on the GoodKnight 425 depend upon the device itself and the mode of operation.

A pressure sensor, common to both GoodKnight 420S and GoodKnight 425, monitors the output and ambient pressure at the mask providing the patient with the right pressure whatever the altitude.

The GoodKnight 420S and the GoodKnight 425 have the common feature of compliance and hour meters.

7.0 - Summary of Performance Testing

1. Functional testing was performed to confirm that the GoodKnight 425 is capable of meeting its stated performance specifications. The device passed all tests.
2. Testing was performed to confirm that the GoodKnight 425 complies 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.

8.0 - Conclusions

We conclude that the GoodKnight 425 meets the stated performance specifications and criteria outlined in the Reviewers Guidance publications referenced above. We conclude that the device and its accessories will operate safely in its intended environment and will be effective in fulfilling its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2004

Mallinckrodt Développement France
C/O Mr. James Bonds
Nellcor Puritan Bennett
4280 Hacienda Drive
Pleasanton, California 94588-2719

Re: K041819
Trade/Device Name: Puritan Bennett Goodknight 425
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 1, 2004
Received: July 6, 2004

Dear Mr. Bonds:

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.

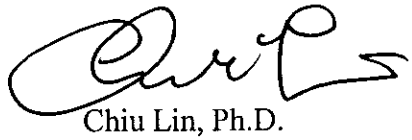
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.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): K041819

Device Name: Puritan Bennett GoodKnight 425

Indications For Use:

The Puritan Bennett GoodKnight 425 is indicated for use in treating obstructive sleep apnea (OSA) in spontaneously breathing patients weighing over 30 kg within a homecare and hospital environment.

Prescription Use XX 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

510(k) Number K041819