JUN - 5 2003

K031470

510(k) SUMMARY

PURITAN BENNETT
GoodKnight 420 Evolution

1. Submitter Information

Tyco Healthcare Nancy
10, Allée Pelletier Doisy
54601 Villers-lès-Nancy
France
FDA Registration #9615679

Submitter's Name : Moustafa Anki
Telephone : +33 383.44.85.00
Fax Number : +33 383.44.85.01

2. Device Name

Proprietary Name : GoodKnight 420 Evolution
Common Name : CPAP System
Device Classification Name : Noncontinuous Ventilator (73 BZD), per 21 CFR 868.5905

3. Predicate Device Equivalence

Puritan Bennett GoodKnight 420S CPAP system, K020886
Puritan Bennett GoodKnight 418P CPAP system, K993584

4. Device Description

The GoodKnight 420 Evolution is designed to deliver Continuous Positive Airway Pressure between 4 and 20 cmH_2O. Power may be supplied either through 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 420 Series is double-insulated so that grounding is not required. The GoodKnight 420 Evolution is set up for use by the homecare dealer using the Clinician Manual provided and operated according to the instructions contained in the Patient Manual. The GoodKnight 420 Evolution relies on a microprocessor for setting and viewing various control parameters and turning features on and off. The microprocessor is also required for the interpretation of various signals from the device including signals relating to patient cycle detection.

The GoodKnight 420 Evolution can operate in either Constant or Automatic mode. In Constant mode, the device delivers a constant positive airway pressure to the patient at a fixed level prescribed by the practitioner between 4 and 20 cmH_2O. In Automatic mode (APAP mode), the practitioner sets a maximum and minimum pressure range above and below the prescribed reference pressure and between 4 and 20 cmH_2O. The pressure is adjusted within this range according to the patient's respiratory pattern and the type of

respiratory events detected. Data concerning the type of events detected, their frequency and duration, etc. is stored in the device data memory and can be accessed by the practitioner through the use of the optional Silverlining™ software. Pressure delivery for the GoodKnight 420 Evolution is regulated by a pressure sensor which monitors both ambient and output pressure and provides feedback to the control system.

The GoodKnight 420 Evolution and accessories are not intended for sterile use. The GoodKnight 420 Evolution and the air filter are intended for multiple use. Accessories such as the patient circuit and nasal masks are for single patient use.

The GoodKnight 420 Evolution uses software to set the various device parameters such as the prescription pressure and the ramp starting pressure. The device can also be connected to a computer via an RS232 serial port, and can be configured from the computer using the optional Silverlining™ software which is required for downloading and displaying compliance data stored in the device memory.

The GoodKnight 420 Evolution is not for use in life-supporting or life-sustaining situations. However, the device can be used to provide the patient with supplemental oxygen. The device is for use by prescription only and displays the appropriate labeling. The device is intended for use in a hospital or homecare environment. The GoodKnight 420 Evolution 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 420 Evolution:

C-PAP Mode	**P-PAP Mode**
On/Off	On/Off
Set Prescription Pressure	Set Initial Pressure
Set Ramp Time	Set Maximum Pressure
Set Ramp Starting Pressure	Set Minimum Pressure
View Hour Meter	Set Ramp Time
View Compliance Meter	Set Ramp Starting Pressure
View Embedded Software Version	Set Maximum Pressure for Apnea Command
	View Hour Meter
	View Compliance Meter
	View Embedded Software Version

5. Intended Use

The intended use of the GoodKnight 420 Evolution is to provide Continuous Positive Airway Pressure between 4 and 20 cmH_2O to spontaneously breathing patients over 30 Kg for the treatment of Obstructive Sleep Apnea in a hospital and homecare environment.

6. Comparison to the Predicate Devices

Both the GoodKnight 420S and GoodKnight 420 Evolution 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. However, the GoodKnight 420 Evolution can also operate in Automatic (APAP) mode, as does the GoodKnight 418P

The global architecture of the GoodKnight 420S and the GoodKnight 420 Evolution is similar. The electrical power requirements for the two instruments are the same. The motor voltage of the GoodKnight 420 Evolution is 13 VDC as is the GoodKnight 420S device. Both devices are double-insulated.

As with the GoodKnight 420S, the GoodKnight 420 Evolution uses a microprocessor to set the various controls. Both devices have a ramp function which, when activated, progressively attains the set reference pressure within a designated time between 0 to 30 minutes.

The user interfaces of the GoodKnight 420S and the GoodKnight 420 Evolution are similar. Both devices use an LCD screen with a four button keypad (one of which is hidden) to access and view various device settings. Available settings on the GoodKnight 420 Evolution depend upon the mode of operation. Both devices have automatic altitude pressure compensation, a compliance meter, and an hour meter. However, the GoodKnight 420 Evolution also has a data storage facility for registering information concerning the patient's respiratory cycle for up to 96 sessions.

7. Summary of Performance Testing

Functional testing was performed to confirm that the GoodKnight 420 Evolution is capable of meeting its stated performance specifications. Testing was performed to confirm that the GoodKnight 420 Evolution complies with the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" published by the Division of Cardiovascular, Respiratory, and Neurological Devices. All software was tested in accordance with the May 29, 1998 "Guidance for the Content of Premarket submissions for Software Contained in Medical Devices" published by the Office of Device Evaluation. Clinical evaluation of the GoodKnight 420 Evolution was performed to demonstrate equivalence of the APAP mode to that of the GoodKnight 418P.

8. Conclusion

The GoodKnight 420 Evolution meets the stated performance specifications and the device and its accessories will operate safely and effectively in fulfilling their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2003

Tyco Healthcare Nancy
C/O Mr. James Bonds
Senior Director, Regulatory Affairs
Tyco Healthcare, LP
Nellcor Puritan Bennett Division
4280 Hacienda Drive
Pleasanton, California 94588

Re: K031470
Trade/Device Name: Puritan Bennett GoodKnight 420 Evolution
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: May 8, 2003
Received: May 9, 2003

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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

K031470

Device Name:

Puritan Bennett *GoodKnight 420 Evolution*

Intended Use:

The Puritan Bennett *GoodKnight 420 Evolution* is intended for use in treating obstructive sleep apnea (OSA) in spontaneously breathing patients weighing over 30 kg within a homecare and hospital environment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

510(k) number: K031470

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

510(k) Number: K031470