K063501

510(k) SUMMARY

PURITAN BENNETT
KnightControl

APR - 6 2007

Submitter Information

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

Submitter's Name	Jean-Paul Arnould Regulatory Affairs Specialist
Telephone	+33 383.44.85.00
Fax	+33 383.44.85.01
Submission Correspondent	James Bonds Senior Director Regulatory Affairs Nellcor Puritan Bennett, Inc. 4280 Hacienda Dr. Pleasanton, CA 94588 USA
Telephone	925-463-4371
Fax	925-463-4020

Date Summary Prepared	February 23, 2007

Device Name

Proprietary Name	KnightControl
Common Name	CPAP Remote Control
Classification Name	Non continuous ventilator (21 CFR 868.5905, Product Code BZD)

Device Information

The KnightControl is an optional accessory that provides remote control capabilities when used in conjunction with the GoodKnight 418, GoodKnight 420, GoodKnight 425, and Knightstar 330 and is intended for use by a clinician in hospital/sleep laboratory settings where patients suffering from obstructive sleep apnea are diagnosed and treated.

Predicate Device Equivalence

This device is substantially equivalent to the ResControl II Remote Control cleared for commercial distribution in K040944. The predicate device is a remote control and data monitoring device intended for use with CPAP systems in the diagnosis and treatment of adult obstructive sleep apnea. It is intended to be used by clinicians in hospital and sleep laboratory environments and is not intended for life support or life-sustaining applications.

Testing was performed to demonstrate that the performance of the KnightControl in its intended environment is as safe and effective as that of the legally marketed predicate device. The safety and effectiveness of the KnightControl was verified through performance related testing that consisted of Electrical Safety, Electromagnetic Compatibility, and Mechanical and Environmental Testing. The KnightControl was found compliant and has been certified to the standards referenced in the "FDA Reviewer Guidance for Premarket Notifications".

Device Description

The KnightControl is designed to control the GoodKnight 418, GoodKnight 420, GoodKnight 425, and Knightstar 330 devices in hospital, sleep laboratories, or other clinical settings.

The KnightControl is powered by AC mains (100 VAC to 240 VAC nominal). The KnightControl is double-insulated so that grounding is not required.

The KnightControl is set up for use by the clinician according to the instructions provided in the manual. The devices are operated according to the instructions contained in their respective Patient Manual and Clinical Manual.

The KnightControl relies on a microprocessor for setting and viewing main control parameters and status of the attached device, and turning features on and off. The microprocessor is also required for getting data of some signals from the devices in order to output these signals to allow these signals to be recorded.

The KnightControl is linked via an RS232 serial port to one of the following devices: GoodKnight 418 series, GoodKnight 420 series, GoodKnight 425 series, or Knightstar 330.

The KnightControl uses software to recognize the device to which it is connected and automatically adapt its menu to the device.

The KnightControl is not for use in life-supporting or life-sustaining situations. The device and it's accessories are not intended for sterile use.

The KnightControl is for multiple use. The KnightControl contains no patient contact components.

The KnightControl is for use in by physicians, nurses, and sleep lab technicians in a clinical (hospital, sleep laboratory, etc.) environment.

The KnightControl does not contain any drugs or biological products as components.

The KnightControl is not part of a kit.

Indication for Use

KnightControl is a remote control for use by clinicians to adjust the settings of the GoodKnight 418, GoodKnight 420, GoodKnight 425, and Knightstar 330 devices.

Intended Use

The KnightControl is a wired remote control intended for use with a GoodKnight 418, GoodKnight 420, GoodKnight 425, or Knightstar 330 device.

This remote control will be used in the sleep lab to titrate sleep breathing disorder patients in order to define parameters of treatment.

The KnightControl is not intended for life support or life-sustaining applications.

Comparison of Technological Characteristics

Both KnightControl and the ResControl II remote control devices have been designed for remote operation and monitoring of CPAP devices by clinicians in clinical environments.

The global architecture of the KnightControl is similar to the ResControl II remote control.
The voltage range for the KnightControl is 100 VAC to 240 VAC or 12 VDC. The KnightControl is double-insulated.

Both the ResControl II and the KnightControl use a microprocessor to set the various controls.

The user interface of the KnightControl and the ResControl II Remote Control control are quite similar. Both devices use an LCD screen with button keypad to access and view various device settings, and output signals for polysomnograph data recording. Available settings on the KnightControl depend upon the connected therapeutic device and the mode of operation.

Summary of Performance Testing

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

Conclusions

We conclude that the KnightControl meets the stated performance specifications and criteria 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

Mallinckrodt Développment France
C/O Mr. James Bonds
Senior Director Regulatory Affairs
Nellcor Puritan Bennett, Incorporated
4280 Hacienda Drive
Pleasanton, California 94588

APR - 6 2007

Re: K063501
Trade/Device Name: KnightControl Remote Control
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 27, 2007
Received: March 29, 2007

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.

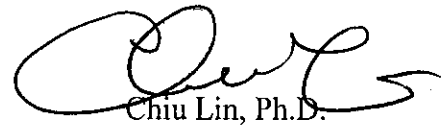
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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:

Device Name: KnightControl Remote Control

Indications For Use:

KnightControl is a remote control for use by clinicians to adjust the settings of the GoodKnight 418, GoodKnight 420, GoodKnight 425 and Knightstar 330 devices.

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)

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[illegible]sion of Anesthesiology, General Hospital,
[illegible]ection Control, Dental Devices

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