JUL 22 1998

K980365

510(k) SUMMARY

NELLCOR PURITAN BENNETT
GoodKnight 418 CPAP System

1.0 Submitter Information

Nellcor Puritan Bennett Inc.
2800 Northwest Blvd.
Minneapolis, MN 55441

Submitter's Name: Stephen Theissen
Phone: (612) 694-3819
Fax Number: (612) 694-3600
Preparation Date: January 05, 1998

2.0 Device Name

Proprietary Name: GoodKnight 418 CPAP System (GK418)

Common Name: CPAP Machine

Classification Name: Noncontinuous Ventilator (73 BZD), per 21 CFR 868.5905

3.0 Predicate Device Equivalence

We are claiming substantial equivalence to the Nellcor Puritan Bennett GoodKnight 318, cleared for commercial distribution per K960518.

4.0 Device Description

The GoodKnight 418 CPAP System is a device used to provide Continuous Positive Airway Pressure between 4 and 18 cmH_2O.

The device is powered by AC Mains from 96 to 138 VAC, 60 Hz. The blower motor nominal voltage is 160 VDC, which is obtained by rectifying and filtering the nominal mains power voltage of 120 VAC. The device is double-insulated so that grounding is not required.

The device is set up for use by the homecare dealer using the Set-up Instructions provided with the device. It is operated by following directions in the Patient Guide. Pocket Cards are also provided for both the patient and the homecare dealer as a convenience.

The pressure is set to the prescription with the use of a patient circuit, with the pressure being measured at the patient end of the circuit. By using this method, losses associated with the patient circuit are compensated for and, thus, the device does not require a pressure transducer.

The device uses a microprocessor to set the various control parameters, turn features on and off and view the set parameters.

Pressure regulation is accomplished by maintaining a constant motor speed. This is done by the microprocessor counting the motor RPM pulses and then changing the motor speed voltage supplied to the motor drive circuit as required to maintain constant speed.

The GoodKnight 418 has the following functions:

- On/Off
- Calibration
- Set Prescription Pressure
- Check Prescription Pressure
- Enable/Disable Ramp Feature
- Set Ramp Starting Pressure
- Start Ramp Feature
- Enable/Disable Altitude Compensation Feature
- Compensating for Changes in Altitude

The accessories, i.e., the patient tubing, patient masks and headgear are the same ones used with the GoodKnight 318.

The device is not for use in life-supporting or life-sustaining situations.

Neither the device nor its accessories are sterile.

The device itself and the air filter are for multiple use. The other accessories, i.e., the patient circuit and nasal masks are for single patient use.

The device is for prescription use and contains appropriate labeling.

The device is for use in a homecare environment.

The device does not contain a drug or biological product as a component. However, it can be used to provide the patient with supplemental oxygen.

The device is not part of a kit.

Software is used to set the various device parameters such as the prescription pressure and the ramp starting pressure, and to enable/disable the ramp and altitude compensation features.

The device is electrically operated.

The device complies with certain voluntary standards, specifically the draft ARDB Reviewer Guidance for Premarket Notification Submissions (Nov 1993) and CAN/CSA C22.2 No. 601.1-M90 (1994).

5.0 Intended Use

The intended use of the GoodKnight 418 is to provide Continuous Positive Airway Pressure (CPAP) between 4 and 18 cmH_2O to spontaneously breathing patients over 30 kg for the treatment of Obstructive Sleep Apnea in a homecare environment.

6.0 Comparison of Technological Characteristics

The voltage range for the GoodKnight 418 is 120VAC nominal. For the GoodKnight 318 the range is 110-240 VAC nominal. The 418 has a motor voltage of 160 VDC instead of 24 VDC as does the 318. The 418 is double-insulated whereas the 318 requires grounding.

The GoodKnight 418 uses a microprocessor to set the various controls whereas the GoodKnight 318 uses mechanical means such as a potentiometer to set prescription pressure and DIP switches to set the ramp parameters. The GoodKnight 418 has a fixed ramp duration of 15 minutes whereas the GoodKnight 318 has a ramp duration of 5, 10 or 20 minutes depending on the DIP switch settings. Also, the 418 has a variable ramp starting pressure, from 3.9 cmH_2O up to the prescription pressure, whereas the 318 has a fixed ramp starting pressure. For both devices, these parameters are within the same range and are thus are not clinically significant.

The GoodKnight 418 has an Altitude Compensation feature whereas the GoodKnight 318 does not. To read the control settings on the GoodKnight 418 CPAP System, the user presses various buttons and counts the number of times the Indicator Lamp flashes, whereas with the GoodKnight 318 the user reads the pressure gage and looks at the DIP switch settings.

The lowest pressure available with the GoodKnight 418 is 1.0 cmH_2O higher than with the GoodKnight 318.

The GoodKnight 418 does not have a compliance meter whereas the GoodKnight 318 has one as optional equipment.

The GoodKnight 418 uses a microprocessor to set and read the control settings whereas the GoodKnight 318 uses analog technology to perform these functions.

7.0 Summary of Performance Testing

7.1 Functional testing was performed to confirm that the GoodKnight 418 is capable of meeting its stated performance specifications. The device passed all tests.

7.2 Testing was performed to confirm that the GoodKnight 418 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.

7.3 All software was tested in accordance with the August 29, 1991 "Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k)Review" published by the Office of Device Evaluation. The device passed all tests.

7.4 No clinical studies were required to support a substantial equivalence determination.

8.0 Conclusions

We conclude that the GoodKnight 418 meets its stated performance specifications and criteria outlined in the Reviewers Guidance publications referenced above. We conclude that the device 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 22 1998

Mr. Stephen G. Theissen
Nellcor Puritan Bennett, Inc.
2800 Northwest Boulevard
Minneapolis, MN 55441-2625

Re: K980365
GoodKnight 418 CPAP System
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: April 29, 1998
Received: May 4, 1998

Dear Mr. Theissen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K980365

Device Name: GoodKnight 418 CPAP System

Indications for Use:

The GoodKnight 418 CPAP System is indicated for use in treating obstructive sleep apnea (OSA) in spontaneously breathing patients weighing over 30 kg within a homecare environment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

Prescription Use ✓ (Division Sign-Off) Over-The-Counter Use ____

Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number _____