K991150

APR 14 1999

510(k) SUMMARY

NELLCOR PURITAN BENNETT
GoodKnight 418G

1.0 - Submitter Information

Nellcor Puritan Bennett France Développement
10, Allée Pelletier Doisy
54601 Villers-lès-Nancy
France

Submitter's Name : Moustafa Anki
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Fax Number : +33 383.44.85.01
Preparation Date : March 31, 1999

2.0 - Device Name

Proprietary Name : GoodKnight 418G
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 418 CPAP System, cleared for commercial distribution per K980365.

4.0 - Device Description

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

The device is powered either by AC mains (115 VAC or 230 VAC nominal) or by an external 24 VDC battery. The blower motor nominal voltage is 24 VDC, which is obtained directly from the external battery or by rectifying and filtering the nominal mains power. The device is double-insulated so that grounding is not required.

The device is set up for use by the homecare dealer using the Clinician Manual provided with the device. It is operated by following the directions in the Patient Manual.

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 418G 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
- Check Compliance Meter
- Reset Compliance Meter
- Check Hour Meter

The accessories, i.e. the patient tubing, patient masks and headgear are the same ones used with the GoodKnight 418 CPAP System.

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. Software is also used to increase the hour meter and the compliance meter.

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 IEC 601-1.

5.0 - Intended Use

The intended use of the GoodKnight 418G is to provide Continuous Positive Airway Pressure (CPAP) between 4 and 18 cmH_2O to spontaneously breathing patient 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 418G is 115 VAC nominal, 230 VAC nominal or 24 VDC. For the GoodKnight 418 CPAP system the voltage is only 115 VAC nominal. The 418G has a motor voltage of 24 VDC instead of 160 VDC as does the 418 CPAP System. Both the 418G and the 418 CPAP System are double-insulated.

Both the 418G and the 418 CPAP System use a microprocessor to set the various controls. The GoodKnight 418 CPAP System has a fixed ramp duration of 15 minutes whereas the GoodKnight 418G has a ramp duration that can be chosen within the following values of 5, 10, 15, 20, 25 or 30 minutes. For both devices, the ramp starting pressure can be set from 4 cmH_2O up to the prescription pressure.

Both the 418G and the 418 CPAP System have an Altitude Compensation Feature.

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 418G, the user presses various buttons and reads the control settings on an LCD screen.

Both the 418G and the 418 CPAP System have a pressure range of 4 to 18 cmH_2O.

The GoodKnight 418 CPAP System does not have a compliance meter whereas the GoodKnight 418G has a compliance meter and an hour meter.

7.0 - Summary of Performance Testing

1. Functional testing was performed to confirm that the GoodKnight 418G is capable of meeting its stated performance specifications. The device passed all tests.
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.
3. 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. The device passed all tests.
4. No clinical studies were required to support a substantial equivalence determination.

8.0 - Conclusions

We conclude that the GoodKnight 418G 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

APR 14 1999

Mr. Moustafa Anki
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10, allée Pelletier Doisy
F-54601 Villers-lès-Nancy celex
FRANCE

Re: K991150
Nellcor Puritan Bennett GoodKnight 418G CPAP Device
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: March 31, 1999
Received: April 6, 1999

Dear Mr. Anki:

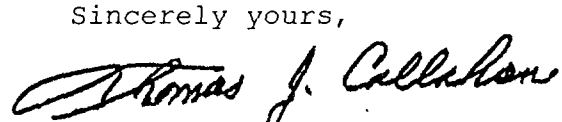
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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

Statement of Intended Use

Device Name :

Nellcor Puritan Bennett, *GoodKnight 418G*

Intended Use :

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

Concurence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

510(k) number: K991151

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____