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510(k) SUMMARY

MALLINCKRODT GoodKnight 418 SERIES

1.0 - Submitter Information

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Preparation Date : October 1999

2.0 - Device Name

Proprietary Name : GoodKnight 418A
: GoodKnight 418P
Common Name : CPAP Machine
Device 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 418G CPAP device, cleared for commercial distribution as per K991150.

4.0 - Device Description

The GoodKnight 418 Series Devices consist of the following elements:

- GoodKnight 418 A (GK418A) C-PAP Machine;
- GoodKnight 418 P (GK418P) C-PAP Machine.

The GoodKnight 418 Series Devices are designed to deliver Continuous Positive Airway Pressure between 4 and 18 cmH₂O.

The GoodKnight 418 Series Devices can be 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 GoodKnight 418 Series Devices are double-insulated so that grounding is not required.

The GoodKnight 418 Series Devices are 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 418 Series Devices 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.

The GoodKnight 418 Series Devices can operate in either Constant or Automatic mode. In Constant mode, the main function of each device is to deliver constant positive airway pressure to the patient at a fixed level prescribed by the practitioner and between 4 and 18 cmH₂O.

In Automatic mode (A-PAP for the GoodKnight 418A and P-PAP for the GoodKnight 418P), the practitioner determines and sets a maximum and minimum pressure range above and below the prescribed reference pressure and between 4 and 18 cmH₂O. The pressure is adjusted within the maximum and minimum limits according to the patient's respiratory pattern and the type of 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™2 software.

Pressure delivery for the GoodKnight 418 Series Devices is regulated by a pressure sensor which monitors both ambient and output pressure at the patient's mask and provides feedback to the control system.

The GoodKnight 418A also uses the signal from the pressure sensor to detect the patient's respiratory cycle and any acoustical vibrations (snoring). However, the GoodKnight 418P has the additional feature of a flow sensor which monitors the patient's respiratory flow, the occurrence of obstructive/open airway apnea, hypopnea, leaks and flow limitation.

The following functions are available on the GoodKnight 418A:

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

A-PAP Mode

- On/Off
- Set Initial Pressure
- Set Maximum Pressure
- Set Minimum Pressure

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

The following functions are available on the GoodKnight 418P:

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

P-PAP Mode

- On/Off
- Set Initial Pressure
- Set Maximum Pressure
- Set Minimum Pressure

- Set Ramp Time
- Set Ramp Starting Pressure
(available only if Ramp Time is not set to 0)
- Set Hypopnea Command
- Set Maximum Pressure for Apnea Command
- Open Airway Apnea Command
- View Hour Meter
- View Compliance Meter
- View Embedded Software Version

The GoodKnight 418 Series Devices use the same pass over humidifier and masks as those approved for use with the GoodKnight 418G. The GoodKnight 418 Series Device tubing is equivalent to that of the GoodKnight 418G with the exception of an additional internal tube used for measuring the pressure at the patient's mask.

The GoodKnight Control clinical remote is also available for use with the GoodKnight 418 Series Devices. The remote is used by the practitioner to configure the devices from a distance via a serial link.

The GoodKnight 418 Series Devices can also be connected to a computer via an RS232 serial port. The devices can be configured from the computer using the Silverlining™2 software which is required for downloading and displaying compliance data stored in the device memory.

The GoodKnight 418 Series Devices are not for use in life-supporting or life-sustaining situations. The devices and/or their accessories are not intended for sterile use.

The GoodKnight 418 Series Devices and the air filter are for multiple use. Accessories such as the patient circuit and nasal masks are for single patient use.

The GoodKnight 418 Series Devices are for use by prescription only and display the appropriate labeling.

The GoodKnight 418 Series Devices are for use in a hospital and homecare environment.

The GoodKnight 418 Series Devices do not contain any drugs or biological products as components. However, the devices can be used to provide the patient with supplemental oxygen.

The GoodKnight 418 Series Devices are not part of a kit.

The GoodKnight 418 Series Devices use software to set the various device parameters such as the prescription pressure and the ramp starting pressure. Software is also used to increase and decrease the pressure level according to the respiratory pattern of the patient when the device is in Automatic mode.

The GoodKnight 418 Series Devices are electrically operated.

The GoodKnight 418 Series Devices comply with certain voluntary standards, specifically the draft ARDB Reviewer Guidance for Premarket Notification Submissions (Nov 1993) and IEC 60601-1.

5.0 - Intended Use

The intended use of the GoodKnight 418 Series Devices is to provide Continuous Positive Airway Pressure (C-PAP) between 4 and 18 cmH₂O to spontaneously breathing patients over 30 Kg for the treatment of Obstructive Sleep Apnea in a hospital and homecare environment.

6.0 - Comparison of Technological Characteristics

The GoodKnight 418G, GoodKnight 418A and GoodKnight 418P are all C-PAP devices which deliver a constant positive air pressure to the patient at a level prescribed by the practitioner between 4 to 18 cmH₂O (C-PAP mode). However, the GoodKnight 418 Series Devices can also operate in Automatic mode. In Automatic mode, maximum and minimum pressure ranges are set, for each type of event, above and below the prescribed reference pressure and between 4 to 18 cmH₂O.

The global architecture of the GoodKnight 418G and the GoodKnight 418 Series Devices is similar. The voltage range for the GoodKnight 418 Series Devices is 115 VAC nominal, 230 VAC nominal or 24 VDC as for the GoodKnight 418G. The motor voltage of the GoodKnight 418 Series Devices is 24 VDC as is the GoodKnight 418G device. The GoodKnight 418G and the GoodKnight 418 Series Devices are all double-insulated.

As with the GoodKnight 418G, the GoodKnight 418 Series Devices use a microprocessor to set the various controls. In common with the GoodKnight 418G, the GoodKnight 418 Series 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 G and the GoodKnight 418 Series Devices are similar. All three 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 418 Series Devices depend upon the device itself and the mode of operation.

The Altitude Compensation feature of the GoodKnight 418G is not a characteristic of the GoodKnight 418 Series Devices. A pressure sensor, common to both GoodKnight 418A and P devices, monitors the output and ambient pressure at the mask providing the patient with the right pressure whatever the altitude.

Unlike the GoodKnight 418G where pressure delivery is regulated by motor speed, the GoodKnight 418 Series Devices regulate pressure delivery according to the pressure sensor feedback signal. The GoodKnight 418A also relies on the pressure sensor for patient cycle detection. However, the GoodKnight 418P, has the additional feature of a flow sensor which is used for the detection of respiratory events as well as leaks and flow limitation.

The GoodKnight 418G and the GoodKnight 418 Series Devices have the common feature of compliance and hour meters. However, the GoodKnight 418 Series also has a data storage facility for registering information concerning the patient's respiratory cycle for up to 100 sessions. The data memory can be accessed by connecting a PC to the RS232 type interface at the back of the device and through the use of the Silverlining™2 software.

The GoodKnight 418G requires calibration prior to use. The GoodKnight 418 Series Devices do not require calibration.

7.0 - Summary of Performance Testing

1. Functional testing was performed to confirm that the GoodKnight 418 Series Devices are capable of meeting their stated performance specifications. The series passed all tests.
2. Testing was performed to confirm that the GoodKnight 418 Series Devices comply with the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" published by the Division of Cardiovascular, Respiratory, and Neurological Devices. The devices 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 devices passed all tests.
4. Clinical studies for the GoodKnight 418 Series Devices were required to support a substantial equivalence determination.

8.0 - Conclusions

We conclude that the GoodKnight 418 Series Devices meet the stated performance specifications and criteria outlined in the Reviewers Guidance publications referenced above. We conclude that the devices and their accessories will operate safely in their intended environment and will be effective in fulfilling their intended use.



Food and Drug Administration
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MAR - 7 2000

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Re: K993584
GoodKnight 418A and GoodKnight 418P
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: February 16, 2000
Received: February 18, 2000

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 (Pre-market 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 pre-market 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.

Page 2 - Mr. Moustafa Anki

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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
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Office of Device Evaluation
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Enclosure

