JAN 1 0 2005

K042184

510(k) SUMMARY

PURITAN BENNETT

GoodKnight H_2O Heated Humidifier

1.0 - Submitter Information

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

Submitter's Name	: Moustafa Anki
Telephone	: +33 383.44.85.00
Fax Number	: +33 383.44.85.01
Preparation Date	: June 2004

2.0 - Device Name

Proprietary Name	: GoodKnight H_2O
Common Name	: Heated Humidifier
Device Classification Name	: Respiratory Gas Humidifier (BTT), per 21 CFR 868.5450

3.0 - Predicate Device Equivalence

We are claiming substantial equivalence to the Respironics H2 Heated Humidifier, cleared for commercial distribution per K030090.

4.0 - Indications for Use

The Puritan Bennett GoodKnight H20 is an accessory intended to warm and add moisture to the inspiratory gas flow for administration to a patient undergoing CPAP or bi-level therapy.

It is intended for use with adult patients receiving CPAP or Bi-level therapy for the treatment of Obstructive Sleep Apnea in the homecare and hospital environments.

5.0 - Device Description

The GoodKnight H_2O is a microprocessor-controlled heated passover humidifier used to provide evaporated water content to dry breathing gases, during treatment of Obstructive Sleep Apnea.

The GoodKnight H_2O has an ABS enclosure and a heater plate positioned in the front of the unit. A humidification chamber slides onto the heater plate and is held in place by a rim on the enclosure. The unit controls are located at the back of the device.

The technological characteristics of the GoodKnight H_2O Heated Humidifier are equivalent to that of the predicate device.

The GoodKnight H_2O is equivalent in terms of type (heated passover humidification), configuration (chamber, mounting arrangements), environmental conditions of use and control method (software).

Non-clinical testing of the GoodKnight H_2O has been carried out and covered mechanical safety, electrical safety, thermal safety, EMC, software verification and validation and performance.

The GoodKnight H_2O meets the performance and safety requirements of ISO 8185 related to humidification systems and which includes also the requirements of IEC 60601-1. The product complies also to the relevant USA deviations from UL 2601-1 and to the applicable requirements of the FDA Reviewers Guidance (November 1993).

6.0 - Conclusion

We conclude that the GoodKnight 425 meets the stated performance specifications and criteria outlined in the Reviewers Guidance and standards 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

JAN 10 2005

Mallickrodt Development France
C/O Ms. Patricia Murphy
Responsible Third Party Official
KEMA Quality B.V.
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K042184
Trade/Device Name: Puritan Bennett GoodKnight H_2O
Regulation Number: 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: December 27, 2004
Received: December 28, 2004

Dear Ms. Murphy:

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.

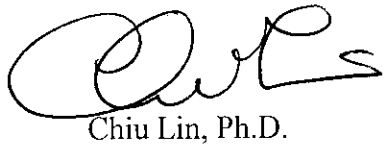
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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 (if known): K042184

Device Name: Puritan Bennett GoodKnight H_2O

Indications For Use:

The Puritan Bennett GoodKnight H2O is an accessory intended to warm and add moisture to the inspiratory gas flow for administration to a patient undergoing CPAP or bi-level therapy.

It is intended for use with adult patients receiving CPAP or Bi-level therapy for the treatment of Obstructive Sleep Apnea in the homecare and hospital environments.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K042184