1072

510(k) Summary

August 23, 2009

exact
PRECISION DENTAL SUPPLIES

K093340

JUN 11 2010

Exact Supplies Ltd
The Stables
Brightwell Baldwin
Oxfordshire, OX49 5NP
UK

Establishment Registration Number:
510(k) Number:

Contact Person: Jonathan Parkinson
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Address: The Stables
Brightwell Baldwin
Oxfordshire, OX49 5NP

Device
Trade Name: PAsr QuietNite
Common Name: Anti-Snoring/Sleep Apnea Device
Classification Name: Device, Anti-Snoring
Product Code: LRK
Class: II
Regulation Number: 872.5570

European CE mark: Approved

European Patent: Granted
USA Patent: Pending

Description of Device:
The PAsr QuietNite, a dentist prescribed mandibular repositioning device, is worn during sleep and is indicated for persons 18 years or older, who wish to reduce the incidence of snoring and/or mild to moderate obstructive sleep apnea. Before a dentist prescribes a PAsr QuietNite appliance for treatment, it is recommended that the patient receive a medical/dental examination including a sleep study diagnosis to determine the need for a PAsr QuietNite appliance.

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Intended Use:

The PAsr/QuietNite, a dentist prescribed mandibular repositioning/advancement device is intended for the treatment of nighttime incidents of snoring and/or mild to moderate obstructive sleep apnea in persons 18years of age or older.

These devices are not indicated for the treatment of central apnea or severe obstructive sleep apnea and should only be prescribed by a Dentist after the undertaking of a sleep study.

Identification of Legally Marketed Device, (predicate) for Substantial Equivalence:

Name: SilentNite
K Number: K972424
Date Cleared: 9/18/1997

Technological Characteristics Summary:

Similarities between both devices are the following:

- ✓ Indications for use
- ✓ Function - Mandibular Repositioning Device
- ✓ Single Patient
- ✓ Multi-Use
- ✓ Prescription Device
  - Custom Fabricated (Fit) from Common Orthodontic Appliance Materials/Techniques
  - Adjustable
- ✓ Environment - Home/Sleep Laboratories
  - Removable
  - Non Sterile
- ✓ Identical Materials

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jonathan Parkinson
Exact Supplies Limited
The Stables, Brightwell Baldwin
Watlington, Oxfordshire
United Kingdom OX49 5NP

JUN 11 2010

Re: K093340
Trade/Device Name: PAsr/QuietNite
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: April 20, 2010
Received: June 9, 2010

Dear Mr. Parkinson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Form
Indications for Use
510(k) Number (if known): _____

Device Name: PAsr/QuietNite

Indications for Use:

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These devices are not indicated for the treatment of central apnea or severe obstructive sleep apnea and should only be prescribed by a Dentist after the undertaking of a sleep study.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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