K083400

510(k) SUMMARY

DEC 11 2008

DenTek Oral Care Inc.'s
Custom Comfort Nightguard

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: November 17, 2008

Name of Device and Name/Address of Sponsor

Custom Comfort Nightguard

DenTek Oral Care, Inc.
307 Excellence Way
Maryville, TN 37801
Phone: (865) 983-1300
Facsimile: (865) 983-2444

Common or Usual Name

Nightguard

Classification Name

Mouthguard, Over-the-Counter

Classification Product Code

OBR

Predicate Devices

DenTek Oral Care Inc.'s DenTek Nightguard (K063483)

Purpose of the Special 510(k) notice.

The Custom Comfort Nightguard is a modification to DenTek Oral Care Inc.'s DenTek Nightguard (K063483).

Intended Use

DenTek's Custom Comfort Nightguard is indicated for use for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Technological Characteristics

The Custom Comfort Nightguard is a fully occlusive nightguard, consisting of a soft, formable material, and non-formable base, which cushions the teeth. When heated and then briefly cooled, the formable material is molded to fit the user's maxillary dentition for maximum retention. The hard base prevents bite-through by users with moderate to severe nocturnal bruxing and cushions the teeth on all occlusal surfaces. The Custom Comfort is designed with an anterior area formed from the soft, formable material that allows for expansion and contraction of the device to fit most mouth sizes.

Substantial Equivalence

DenTek's Custom Comfort has the same intended use and similar indications, principles of operation, and technological characteristics as the DenTek Nightguard. The minor modification made in the device does not raise any new questions of safety or effectiveness. Thus, the Custom Comfort is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DenTek Oral Care, Incorporated
C/O Mr. Howard M. Holstein
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, North West
Washington, DC 20004

DEC 11 2008

Re: K083400
Trade/Device Name: Custom Comfort Nightguard
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OBR
Dated: November 17, 2008
Received: November 17, 2008

Dear Mr. Holstein:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083400

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Custom Comfort Nightguard

Indications for Use:

The Custom Comfort Nightguard is indicated for use for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Prescription Use _____ AND/OR Over-The-Counter Use_X_
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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