K063483

510(k) SUMMARY

DenTek Oral Care's NightGuard

JAN 2 3 2007

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

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

Date Prepared: November 16, 2006

Name of Device and Name/Address of Submitter and Sponsor

DenTek NightGuard

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

Common or Usual Name

Dental Protector

Classification Name

Unclassified

Predicate Devices

The Doctor's NightGuard (K053580)

Intended Use / Indications for Use

The DenTek NightGuard is indicated 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 teeth grinding.

Technological Characteristics

The DenTek NightGuard is composed of a soft, formable material made of a blend of ethylene vinyl acetates, and non-formable occlusal base, which cushions the teeth. The base is composed of a copolymer of ethylene and methyl acrylate. When heated and then briefly cooled, the formable material is molded to fit the user's upper teeth 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 DenTek NightGuard is designed with three flex points that allow for expansion and contraction of the device to fit most mouth sizes.

Performance Data

No performance data is required in support of this 510(k) notice.

Substantial Equivalence

The DenTek NightGuard is substantially equivalent to The Doctor's NightGuard. The DenTek NightGuard has the same intended uses, indications and principles of operation, and similar technological characteristics as its predicate device. The minor technological differences between the DenTek NightGuard and its predicate device raises no new questions of safety or effectiveness. Thus, the DenTek NightGuard is substantially equivalent to The Doctor's NightGuard.

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. Jeffrey Shapiro
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004

JAN 23 2007

Re: K063483
Trade/Device Name: DenTek NightGuard
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MQC
Dated: November 16, 2006
Received: November 17, 2006

Dear Mr. Shapiro:

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 (240) 276-0115. 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/industry/support/index.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

K063483

Indications for Use Statement

510(k) Number (if known):_____

Device Name: **DenTek NightGuard**

Indications for Use:

The DenTek NightGuard is indicated 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 teeth grinding.

Prescription Use ____ AND/OR Over-The-Counter Use X
(Part 21 C.F.R. 801 Subpart D) (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)

K063483