K072147

510(k) SUMMARY

DenTek's Comfort Fit

AUG 30 2007

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

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307 Excellence Way
Maryville, TN 37801
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OR

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Date Prepared: July 27, 2007

Name of Device and Name/Address of Sponsor

DenTek's Comfort Fit 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

Unclassified

Predicate Devices

DenTek Oral Care, Inc.'s NightGuard (K063483)

Power Product Inc.'s Splintek EZ-Splint (K022809)

Purpose of the Special 510(k) Notice

The Comfort Fit is a modification to the DenTek NightGuard.

Intended Use

The Comfort Fit 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 Comfort Fit consists of two bite pads and one buccal retaining strap. The bite pads consist entirely of Elvax, and the buccal retaining strap consists of Elvaloy. The bite pads move along the buccal strap to adjust to the individual user needs with the strap always contained within the wings of the bite pads. There are 4 positions of adjustability for each molar pad. There is a built in wear indicator, which helps the user determine when they need to replace their Comfort Fit.

Substantial Equivalence

The Comfort Fit has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate devices. Thus, the Comfort Fit is substantially equivalent to its predicate devices.

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, Esq.
Regulatory Counsel
Hogan & Hartson, L.L.P
555 13th Street NW
Washington, DC 20004

AUG 30 2007

Re: K072147
Trade/Device Name: DenTek Comfort Fit NightGuard
Regulation Number: Unclassified
Regulation Name: Not Applicable
Regulatory Class: Unclassified
Product Code: OBR
Dated: August 3, 2007
Received: August 3, 2007

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.

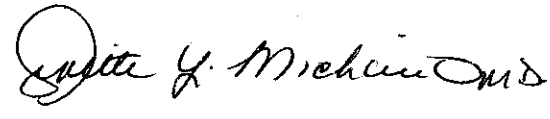
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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 (240) 276-3150 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

K072147

Attachment 9

Indications for Use Statement

Device Name: DenTek Comfort Fit NightGuard

Indications for Use: The DenTek Comfort Fit 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 _____ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use _X_ (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

510(k) Number: K072147