OCT 0 6 2008

K082301

510(k) SUMMARY

Placontrol, Inc.'s Grind No More

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

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Date Prepared: August 12, 2008

Name of Device and Name/Address of Sponsor

Grind No More
Placontrol, Inc.
12760 High Bluff Drive, Suite 210
San Diego, CA 92130

Common or Usual Name

Mouthguard

Classification Name

Mouthguard, Over-the-Counter

Product Code and CFR Provision

OBR, unclassified

Predicate Device

DenTek Oral Care Inc.'s Comfort Fit NightGuard (K072147)

Intended Use / Indications for Use

Grind No More 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

Grind No More is a posterior-only occlusive mouthguard, consisting of two molar bite plates connected by a buccal retention band. Similarly, the predicate device consists of two molar bite areas connected by a retaining band; therefore, the Grind No More device is technologically similar to the predicate device. As a safety feature to aid in device retention, each molar bite plate is grooved with vertical positioners to engage the natural anatomy of the teeth.

Substantial Equivalence

Grind No More is as safe and effective as the predicate device. Grind No More has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between Grind No More and its predicate device raise no new questions of safety or effectiveness. Thus, Grind No More is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 06 2008

Placontrol, Incorporated
C/O Mr. Jonathan S. Kahan
Regulatory Counsel
Hogan & Hartson LLP
555 Thirteenth Street, NW
Washington, DC 20004

Re: K082301
Trade/Device Name: Grind No More
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OBR
Dated: August 12, 2008
Received: September 18, 2008

Dear Mr. Kahan:

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

Indications for Use Statement

510(k) Number (if known): K082301

Device Name: Grind No More

Indications for Use:

Grind No More 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 _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (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)

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

510(k) Number: K082301