6.0 510(K) SUMMARY

Manufacturer	Grind Guard Technologies LLC
Contact Name	Dr. Joseph Pelerin
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E-mail	contact@advantagedentlinc.com
Title	President and CEO
Date	September 15,2008

Proprietary Name	GrindGUARD$_N$
Common Name	Mouthguard
Classification Name	Mouthguard, Prescription
Classification Code	MQC

Predicate Devices

Substantial equivalence is being claimed to:

- The Doctor's Nightguard Advanced Comfort (K073220)
- NTI Tension Suppression System (K010876)
- TAP- anti-snoring device (formerly Quiet Knight) (K962516)
- Temporary Crown Matrix Buttons (K900389)

Description of Device

The GrinGUARD$_N$ is an oral appliance consisting of a rigid outer tray with a dome shape protrusion in the center of the tray, to be situated over the lower incisors and an internal layer, which can be melted at low temperatures and molded to the individuals' teeth. The outer tray is manufactured from polysulfone material and the inner, moldable layer consists of polycaprolactone.

Intended Use

The GrindGUARD$_N$ is a mouth guard intended to protect against grinding and clenching.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 31 2009

Grind Guard Technologies, LLC
Mr. Bill McLain
Principal Consultant
Keystone Regulatory Services, LLC
342 East Main Street, Suite 207
Leola, Pennsylvania 17540

Re: K082723
Trade/Device Name: GrindGUARD$_N$
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MQC
Dated: August 17, 2009
Received: August 20, 2009

Dear Mr. McLain:

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 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/Reporta Problem/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,

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

Enclosure

SECTION 5. INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: GrindGUARD$_N$

Indications for Use: The GrindGUARD$_N$ is a mouth guard intended to protect against grinding and clenching.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K082723