K133037

JAN 23 2014

5 510(k) Summary

5.1 Submission Correspondent and Owner

Submission Correspondent

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Sponsor (Owner)

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5.2 Date Summary Prepared

September 24, 2013

5.3 Device Trade Name

GrindGuard^{N}

5.4 Device common name

Mouthguard. Antibruxing night guard.

5.5 Device classification name

Mouthguard, Over-The-Counter, OBR - Unclassified

5.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

Grindguard Technologies - GrindGuard^{N} (RX) - K082723
SmartGuard, Inc. - SmartGuard Night Guard - K123161

5.7 Description Of The Device

The GrindGuard^{N} is an oral appliance consisting of a thin exterior tray (shell) that covers approximately half of the lower or upper arch, with a dome shape protrusion (in the center of the device), to be situated over the central 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 is formed by injection molding. The inner, formable layer consists of polycaprolactone. The GrindGuard^{N} is designed to prevent night grinding.

After a brief submersion in water which has been heated in the microwave the thermoplastic liner becomes translucent and formable. The patient centers the device over his/her lower front teeth and bites until pressure is felt on upper and lower two front teeth. Gentle pressure is applied to the ends of the GrindGuard^{N} for approximately 2 minutes in order to set the thermoplastic material. The rigid polysulfone outer tray helps the softer material maintain shape and conformity with the teeth while forming the device.

The GrindGuard^{N} is indicated for use as a mouth guard intended to protect against grinding and clenching.

5.8 Technological Characteristics

The GrindGuard^{N} has identical technical characteristics as the predicate devices.

5.9 Non-Clinical Testing

No non-clinical testing was performed for this submission.

5.10 Biocompatibility

Since the materials and methods of construction are identical to the K082723 predicate device, no additional biocompatibility testing was conducted.

5.11 Clinical Testing

No clinical testing was performed in association with this submission.

5.12 Conclusions

The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 23, 2014

Grind Guard Technologies, LLC
C/O Mr. William G. McLain
President and Principal Consultant
Keystone Regulatory Services, LLC
342 E. Main Street, Suite 207
Leola, PA 17540

Re: K133037
Trade/Device Name: GrindGuardN
Regulation Number: Unclassified
Regulation Name: Mouthguard, Over-The-Counter
Regulatory Class: Unclassified
Product Code: OBR
Dated: October 23, 2013
Received: October 25, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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. 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/ReportaProblem/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,

Kwame O. Ulmer -S

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133037

Device Name

GrindGuardN

Indications for Use *(Describe)*

The GrindGuardN is a mouth guard intended to protect against grinding and clenching.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

PSC Publishing Services (301) 443-6740 EF

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