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

September 30, 2015

Den Tek Oral Care, Inc.
Ms. Linda Giles
Regulatory & Compliance Specialist
397 Excellence Way
Maryville, Tennessee 37801

Re: K151149
Trade/Device Name: Ready-Fit Disposable Dental Guard
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OBR
Dated: August 18, 2015
Received: August 21, 2015

Dear Ms. Giles:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

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

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known):__**K151149**_____

Device Name: Ready-Fit Disposable Dental Guard

Indications for Use:

Ready-Fit Disposable Dental Guard is indicated for protection for nighttime teeth grinding or bruxism. It is intended to reduce damage to teeth by cushioning them and keeping them apart during grinding.

Prescription Use _____ (Per 21 C.F.R. 801.109)

AND/OR

Over-The-Counter Use _X_ (Per 21 C.F.R. 801 Subpart C)

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

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5. Traditional 510(k) SUMMARY – K151149

DenTek Oral Care Inc.'s
Ready-Fit Disposable Dental Guard

510(k) Owner's Name, Address, Phone and Fax Number

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

Contact Person and Date Prepared

Linda Giles – Regulatory and Compliance Specialist
Date Prepared: 08/18/2015 revision 2

Subject Device
Device Trade Name: Ready-Fit Disposable Dental Guard
Device Common or Usual Name: dental guard, nightguard
Classification Name: Mouthguard, Over-the-Counter
Product Code and Class: OBR; unclassified

Predicate Device
Trade Name: Grind No More
Applicant: Placontrol Inc.
Classification Name: Mouthguard, Over-the-Counter
Product Code and Class: OBR; unclassified
510(k) Number: K082301

Device Description

Ready-Fit Disposable Dental Guard is a ready-to-wear, posterior-only occlusive mouthguard, with two molar bite surfaces each consisting of three cylinders (bite tubes) connected by a buccal retention band.

Indications for Use/Intended Use

Ready-Fit Disposable Dental Guard is indicated for protection for nighttime teeth grinding or bruxism. It is intended to reduce damage to teeth by cushioning them and keeping them apart during grinding.

Sec. 5 - 510(k) Summary K151149 (cont.)

Technological Characteristics

Ready-Fit Disposable Dental Guard is a posterior-only occlusive mouthguard, with two molar bite surfaces each consisting of three cylinders (bite tubes) connected by a buccal retention band. Similarly the predicate device is a posterior-only occlusive mouthguard, consisting of two molar bite plates connected by a buccal retention band. The cylinders which make up the bite surfaces of the subject device allow the user to engage the guard in the natural anatomy of the teeth, and are substantially equivalent to the predicate device's bite pads, as they serve the same purpose - to cushion the teeth and keep them teeth apart during grinding. The technological/design differences between Ready-Fit Disposable Dental Guard and the predicate device, Grind No Mores, are minor and the subject device is, therefore, technologically similar to the predicate device. Both the subject device and the predicate device are indicated for over-the-counter use and are disposable after one night's use.

Substantial Equivalence

Substantial Equivalence Chart
DenTek Oral Care, Inc.'s Ready-Fit Disposable Dental Guard – K151149

	Ready-Fit Disposable Dental Guard (K151149) Subject Device	Grind No More (K082301) Predicate Device	Conclusion
Indications for Use	Ready-Fit Disposable Dental Guard is indicated for protection for nighttime teeth grinding or bruxism. It is intended to reduce damage to teeth by cushioning them and keeping them apart during grinding.	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.	Equivalent
User Population	OTC, age 18 and up	OTC, age 18 and up	Equivalent
DESIGN			
Technological Characteristics	A posterior-occlusive mouthguard, comprised of two molar bite surfaces, each with 3 cylinders (bite tubes), connected by a buccal retaining strap.	A posterior-occlusive mouthguard, comprised of two molar bite plates, each with alignment grooves, connected by a buccal retaining strap.	Substantially Equivalent[1]
Materials	Comprised completely of EMA material	Comprised completely of EMA material	Equivalent
Fit	One Size Fits All, worn on upper or lower teeth	One Size Fits All, worn on upper or lower teeth	Equivalent

Dimensions (l x w x h)	3.8cm L x 3.9cm W x 1.9cm H	4.5cm L x 3.5cm W x 1.7cm H	Substantially Equivalent[2]
Weight	0.04 ounce	0.06 ounce	Substantially[2] Equivalent
Sterilization	Device is not provided sterile.	Device is not provided sterile.	Equivalent
Method of Disinfection or Cleaning	The device is meant to be discarded after one night's use. No instructions for cleaning are included.	The device is meant to be discarded after one night's use. No instructions for cleaning are included.	Equivalent
Standards with which Device Complies	None specified for Product Code OBR	None specified for Product Code OBR	Equivalent

1. Design differences do not affect substantial equivalence as the technological characteristics of both devices serve the same purpose - to reduce damage to teeth by cushioning them and keeping them apart.
2. The differences in the device dimensions and weight are very small and the devices have a similar overall shape, fit the mouth in a similar manner and have the same function to protect the teeth from the damage of night-time grinding.

Bench Test Results

DenTek conducted an in-home use test (IHUT) during the month of April 2015, to validate that the design of Ready-Fit Disposable Dental Guard meets the intended use and performance of the device. Physical properties testing for density (ASTM D792 - ISO 1183) and melt flow (ASTM D1238 – ISO 1133) have been conducted on the material of the guard, and mechanical properties tests for Shore Hardness A and D (ASTM 2240 – ISO 868), tensile strength and elongation at break and the tensile modulus (ASTM 638 – ISO 527-2) of the material have also been tested.

Conclusion

Ready-Fit Disposable Dental Guard is substantially equivalent to the identified predicate device, Grind No More. Ready-Fit Disposable Dental Guard has the same intended uses, similar indications for use, technological characteristics, principles of operation, and has the same material composition as the predicate device.