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

February 19, 2016

Bite Tech Inc.
c/o Mr. Alex Varond
Regulatory Counsel
Hyman, Phelps & McNamara, P.C.
700 13th Street NW, Suite 1200
Washington, DC 20005

Re: K150492
Trade/Device Name: Ora-GUARD Dental Grind Guard
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: OBR
Dated: December 24, 2015
Received: December 28, 2015

Dear Mr. Varond:

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" (21 CFR 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

II. INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150492

Device Name
Ora-GUARD Dental Grind Guard

Indications for Use *(Describe)*
The Ora-GUARD Dental Grind Guard is a device that is indicated for protection against bruxism, nighttime teeth grinding, and jaw clenching.

It is intended to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY
Ora-GUARD Dental Grind Guard

Submitter Name:	Bite Tech Inc.
Submitter Address:	20 Glover Avenue, Norwalk CT 06850
Contact Person:	Melanie McNichol for Jeff Padovan
Phone Number:	203-202-3239
Fax Number:	203-987-6802
Date Prepared:	February 18, 2016
Device Trade Name:	Ora-GUARD Dental Grind Guard
Device Common Name:	Mouthguard, Over-the-counter
Product Code:	OBR
Regulation Number:	Unclassified
Predicate Device: (K091660)	DenTek Custom Comfort Nightguard Version 2
Device Description:	Ora-GUARD Dental Grind Guard is an over-the-counter dental protector, which is used as a barrier between teeth for individuals who grind their teeth. The Ora-GUARD Dental Grind Guard is intended to be worn while sleeping (e.g., at night or while napping). The material is comfortable to wear, and it can be self-fit by submerging in hot water to make the material malleable to fit on the lower teeth of the oral cavity. Ora-GUARD Dental Grind Guard is constructed of a soft EVA, which contacts the tooth surface and a hard base, which protects bite-through by user when bruxing (polycarbonate). Ora-GUARD Dental Grind Guard is provided in one size that fits most (comfortably fits palate sizes ranging from two to two and one half inches wide).

Intended Use: The Ora-GUARD Dental Grind Guard is a device that is indicated for protection against bruxism, nighttime teeth grinding, and jaw clenching. It is intended to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism.

Performance data: Testing related to the measurement of tooth surface spacing with Ora-GUARD Dental Grind Guard and its ability to neutralize anterior/posterior imbalance of teeth grinding on tooth surfaces was conducted. The physical properties of the materials were identified including flexural strength, water solubility, and shore hardness and determined to be appropriate for its intended use. Measuring the tooth surface spacing with and without the subject device using CAT Scan demonstrated that Ora-GUARD Dental Grind Guard acts as a spacer between the upper and lower tooth surfaces, similar to the DenTek Custom Comfort Nightguard Version 2 (K091660). A biocompatibility assessment was conducted according to ISO 10993-1 on the subject device and cytotoxicity testing according to ISO 10993-5 on the materials was provided.

Summary of Technological Characteristics: The table below (Table III.1) compares the technological characteristics of the Ora-GUARD Dental Grind Guard and the DenTek Custom Comfort Nightguard Version 2 (K091660).

Table III.1: Proposed and Predicate Device Comparison Matrix

Feature Being Compared	**PROPOSED DEVICE**	**PREDICATE DEVICE**	**Similarities and Differences**
	Ora-GUARD Dental Grind Guard (K150492)	**DenTek Custom Comfort Nightguard Version 2 (K091660)**	
Intended Use	Intended to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism.	Intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.	**Same.** Ora-GUARD and the predicate device are intended for use as mouthguards.

Indications for Use	The Ora-GUARD Dental Grind Guard is a device that is indicated for protection against bruxism, nighttime teeth grinding, and jaw clenching. It is intended to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism.	The Custom Comfort Nightguard Version 2 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.	**Same.**
Device Description	Flexible, moldable guard used as a barrier between teeth for bruxism and nighttime teeth grinding.	Flexible, moldable guard used as a barrier between teeth for bruxism and nighttime teeth grinding.	**Same.**
Molding Method	Traditional heat & bite self-fit.	Traditional heat & bite self-fit.	**Same.**
Fit	Lower teeth	Upper Teeth	**Similar.** Performance Testing demonstrates equivalence.
Reusable	Yes, single patient.	Yes, single patient.	**Same.**
Materials	EVA and a hard base (polycarbonate).	EVA and hard base.	**Similar.**
Biocompatibility	Biocompatible	Biocompatible	**Same.**
Sterility	Non-sterile	Non-sterile	**Same.**

The Ora-GUARD Dental Grind Guard, like the predicate device, cushions the teeth and keeps the upper teeth from contacting the bottom teeth. In this way, Ora-GUARD Dental Grind Guard, like the predicate device, acts as a barrier between teeth. The technological characteristics of the Ora-GUARD Dental Grind Guard and the predicate device are similar. The subject device and predicate have slightly different Intended Use language. However, the difference in language does not change the intended use or substantial equivalence. Any minor differences between the Ora-GUARD Dental Grind Guard and predicate device are minor and do not raise issues regarding substantial equivalence.

Conclusion: The Ora-GUARD Dental Grind Guard is substantially equivalent to the predicate device. The Ora-GUARD Dental Grind Guard and the predicate device have the same intended use, indications for use, and principles of operation, and similar technological characteristics. The minor technological differences between the Ora-GUARD Dental Grind Guard (lower jaw product

versus upper jaw product) and its predicate device raise no new questions of substantial equivalence.