Medtech Products Inc.
% Vincent Argiro
Director Regulatory Affairs
Prestige Brands Holdings
660 White Plains Road
Tarrytown, New York 10591

September 17, 2018

Re: K180933
Trade/Device Name: DenTek Ultimate Dental Guard
Regulatory Class: Unclassified
Product Code: OBR
Dated: August 8, 2018
Received: August 9, 2018

Dear Vincent Argiro:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

For Tina Kiang, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
DenTek Ultimate Dental Guard

Indications for Use *(Describe)*
The DenTek Ultimate™ Dental Guard is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and reduce the noise associated with bruxing or grinding.

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.

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MEDTECH

A PrestigeBrands COMPANY

510(k) Summary

DenTek Ultimate™ Dental Guard

K # 180933

1. Submitter

Name & Address:	Medtech Products Inc. 660 White Plains Road Tarrytown, NY, 10591
Contact:	Vincent Argiro, RAC
Title:	Director, Regulatory Affairs
Phone number:	(914) 524-8721
Email:	vargiro@prestigebrands.com

2. Date Prepared

September 14, 2018

3. Device Identification

Trade/Proprietary Name:	DenTek Ultimate™ Dental Guard
Common/Usual Name:	Over-the-Counter Dental Guard
Classification Name:	Mouthguard, Over-the Counter
Regulation Number:	N/A
Product Code:	OBR
Device Class:	Unclassified
Classification Panel:	Division of Anesthesiology, General Surgery, Infection Control and Dental Devices

4. Legally Marketed Predicate Device(s)

Primary Predicate:	DenTek™ Custom Comfort Nightguard Version 2 (K091660), Product Code OBR

Reference Device: DenTek™ New Comfort-Fit Dental Guard (K123849), Product Code OBR

5. Device Description

The DenTek Ultimate™ Dental Guard is a one-piece, posterior-occlusion dental guard consisting of two moldable bite-pads connected by a flexible band that rests behind the user's front teeth. The guard is constructed of a thermoplastic ethylene-vinyl acetate copolymer and is fitted by molding the bite pads to the user's maxillary pre-molars/molars after the guard has been heated via submersion in boiled water. The DenTek Ultimate™ Dental Guard is supplied pre-loaded into a flexible molding tray that allows the user to accurately place and comfortably hold the heated device during the molding process. When in place, the guard maintains separation between upper and lower teeth, reducing noise and damage to the teeth associated with teeth grinding.

6. Intended Use

The DenTek Ultimate™ Dental Guard is an over-the-counter (OTC) device that is intended to be used by lay people to reduce the damage caused by nighttime teeth grinding.

The DenTek Ultimate™ Dental Guard bears the following indications for use statement:

The DenTek Ultimate™ Dental Guard is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and reduce the noise associated with bruxing or grinding.

The DenTek Ultimate ™ Dental Guard intended use statement is identical to that of the predicate devices.

7. Substantial Equivalence Discussion

The following table compares the DenTek Ultimate™ Dental Guard to the chosen predicate and reference devices with respect to intended use and technological characteristics. This comparison of the devices provides detailed information demonstrating the basis for the determination of substantial equivalence. Any minor differences are discussed in the narrative below the table.

Table 5-1: Comparison of Characteristics

	Proposed Device	Predicate Device	Reference Device	Differences
Trade Name / Device Name	DenTek Ultimate™ Dental Guard	DenTek™ Custom Comfort Night Guard Version 2	DenTek™ New Comfort-Fit® Dental Guard	N/A
510(k) Number	K180933	K091660	K123849	N/A
Date Cleared	90 days from date of receipt by FDA	06/12/2009	01/10/2013	N/A
Original applicant	Medtech Products	DenTek Oral Care,	DenTek Oral Care,	N/A

	Inc.	Inc.	Inc.	
REGULATORY CLASSIFICATION				
Regulatory Class	Unclassified	Unclassified	Unclassified	None
Name of Generic Device Type	Mouthguard, Over-the-Counter	Mouthguard, Over-the-Counter	Mouthguard, Over-the-Counter	None
Regulation	N/A	N/A	N/A	None
Product Code	OBR	OBR	OBR	None
Applicable Performance Standards or Special Controls	None specified by FDA for Product Code OBR	None specified by FDA for Product Code OBR	None specified by FDA for Product Code OBR	None
DEVICE DESCRIPTION – SUBSTANTIAL EQUIVALENCE COMPARATORS				
Intended Use	Keep upper and lower teeth separated during sleep.	Keep upper and lower teeth separated during sleep.	Keep upper and lower teeth separated during sleep.	None
OTC or Rx	OTC	OTC	OTC	None
Indications for Use	For protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and reduce the noise associated with bruxing or grinding.	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.	For protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and reduce the noise associated with bruxing or grinding.	None
Target Population	Adults 18 and older	Adults 18 and older	Adults 18 and older	None
Technological Characteristics	Flexible, moldable guard used as a barrier between teeth.	Flexible, moldable guard used as a barrier between teeth.	Flexible, adjustable guard used as a barrier between teeth.	Same as predicate
DEVICE DESCRIPTION – DESIGN FEATURES				
Contact Materials	Ethylene-vinyl acetate copolymer	Ethylene-vinyl acetate copolymer	Ethylene-vinyl acetate copolymer	Minor (similar to both cited devices)
Other Materials	None	Ethylene and methyl acrylate copolymer	None	Same as reference
Design /	Posterior	Full occlusion, boil-	Posterior	Minor (similar to

Presentation	occlusion, boil-and-fit dental guard	and-fit dental guard	occlusion, ready-to-wear dental guard	both cited devices)
Method of Manufacture	Injection molding	Injection molding	Injection molding	None
Method of Cleaning	Toothpaste or mouthwash, brush followed by cool water rinse.	Toothpaste or mouthwash, brush followed by cool water rinse.	Toothpaste or mouthwash, brush or effervescent cleaning tablet/powder followed by cool water rinse.	Same as predicate
Fit	One size fits all via traditional heat and bite.	One size fits all via traditional heat and bite.	One size fits all via adjustable bite pad-position.	Same as predicate
Dimensions (L x W x H)	30.1 mm x 61.9 mm x 12.01 mm	42 mm x 64.8 mm x 11.15 mm	40 mm – 48 mm x 42 mm x 16 mm	Minor (similar to both cited devices)
Weight	3.2 grams	7.8 grams	2.5 grams	Minor (similar to both cited devices)
Fitting Tray Included	Yes	Yes	No	Same as predicate
Accessories	Storage case	Storage case	Storage case	None
Multiple Use Device	Yes	Yes	Yes	None
Sterile Device	No	No	No	None
Leaflet included	Yes	Yes	Yes	None
Use environment	Home	Home	Home	None
Anatomical site of use	Oral Cavity	Oral Cavity	Oral cavity	None

The table above identifies a few minor differences between the proposed device and the cited predicate and reference devices. While the contact material for all devices is an ethylene-vinyl acetate copolymer, the specific copolymer used in the proposed device has an ethylene-to-vinyl acetate ratio that falls between the ratios used in the predicate and reference devices. Also, the design of the proposed device blends the boil-and-fit molding method of the predicate with the posterior-occlusion format of the reference device. Finally, though not identical, the measurements of the proposed guard are similar to both cited devices (i.e., the bite radius and vertical profile dimensions are within 10% of the predicate device, but with a lesser depth due to the partial-occlusion design, and the weight of the proposed product falls between the weights of the other two devices).

In accordance with section 513(i)(1)(A) of the FDCA, a device is substantially equivalent (SE) when it has the same intended use and technological characteristics as a legally marketed predicate device. As demonstrated in this traditional 510(k), any differences between the subject device and the cited predicate are minor and do not raise different questions of safety or effectiveness and this application establishes that the device is as safe and effective as the predicate. It is on this basis that DenTek Ultimate™ Dental Guard is SE to the cited predicate device.

8. Non-Clinical Performance Data

The following bench testing was conducted to confirm the performance of the DenTek Ultimate™ Dental Guard:

- *Impression test*. Simulation study demonstrating the finished guard's ability to take a distinct impression of the teeth when molded as directed.
- *Separation test*. Simulation study demonstrating the finished guard's ability to keep the teeth separated when the jaw is clenched.
- *Stability test*. Simulation study demonstrating the finished guard's ability to stay in place after fitting.
- *Comparative wear test*. Simulation study demonstrating the finished guard's durability is equivalent to that of the cited predicate device. (Note: This study was used to support the labeled six-month usable life of the DenTek Ultimate™ Dental Guard, which matches that of the predicate device.)

The non-clinical testing of DenTek Ultimate™ Dental Guard demonstrates the device's performance providing a distinct impression of the teeth, separation, security and expected use life and therefore supports the substantial equivalence to the cited predicate.

Additionally, the following tests for biocompatibility were conducted on both the DenTek Ultimate™ Dental Guard and the provided forming tray:

- *In Vitro* Cytotoxicity Assay (Elution method) in accordance with ISO 10993-5;
- Guinea Pig Maximization Test (Sensitization) in accordance with ISO 10093-10, Section 7.5 and Annex E;
- Oral Mucosa Irritation Test in accordance with ISO 10993-10 Annex B.3.

These studies demonstrated that DenTek Ultimate™ Dental Guard and the forming tray were not cytotoxic, were not contact skin sensitizers, and were not irritating to the buccal mucosa, which further supports the device's substantial equivalence to the predicate.

9. Clinical Performance Data

There are no differences in intended use and technological characteristics between the DenTek Ultimate Dental Guard and the predicate that necessitate conducting a clinical trial.

10. Statement of Substantial Equivalence

As demonstrated in this application, the proposed device, the DenTek Ultimate™ Dental Guard, has the same intended use as the identified predicate device, DenTek™ Custom Comfort Nightguard Version 2 (K091660), and employs the same basic technological characteristics; any differences between the proposed device and the predicate are minor and do not constitute different technological characteristics. The relevant information on biocompatibility and the performance testing confirm the DenTek Ultimate™ Dental Guard fulfills its intended use as safely and effectively as the legally marketed predicate device. The DenTek Ultimate™ Dental Guard is therefore substantially equivalent to the cited predicate.