December 22, 2020

Vincent Argiro
Director, Regulatory Affairs
Medtech Products, Inc.
660 White Plains Rd.
Tarrytown, New York 10591

Re: K202974
Trade/Device Name: DenTek Fresh Protect Dental Guard
Regulatory Class: Unclassified
Product Code: OBR
Dated: September 29, 2020
Received: September 30, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K202974

Device Name
DenTek™ Fresh Protect™ Dental Guard

Indications for Use *(Describe)*
The DenTek™ Fresh Protect™ 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.

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MEDTECH

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510(k) Summary

DenTek™ Fresh Protect™ Dental Guard

K # K202974

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

December 21, 2020

3. Device Identification

Trade/Proprietary Name:	DenTek™ Fresh Protect™ 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)

Predicate Device:	DenTek™ Ready-Fit™ Disposable Dental Guard (K151149), Product Code OBR

5. Device Description

The DenTek™ Fresh Protect™ Dental Guard is an over-the-counter (OTC) device to be used by lay people for protection against the effects of nighttime teeth grinding. The guard is constructed of an ethylene/vinyl acetate copolymer and utilizes a ready-to-wear, one-size-fits-all design. The fully occlusive guard is worn on the lower teeth, maintaining separation between the upper and lower teeth, thereby preventing the noise and damage associated with teeth grinding.

6. Intended Use

The DenTek™ Fresh Protect™ Dental Guard is an over-the-counter (OTC) device that is intended to be used by lay people for protection against the effects of nighttime teeth grinding.

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

The DenTek™ Fresh Protect™ 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™ Fresh Protect™ Dental Guard intended use statement is identical to that of the predicate device.

7. Substantial Equivalence Discussion

The following table compares the DenTek™ Fresh Protect™ Dental Guard to the chosen predicate device 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	Differences
Trade Name / Device Name	DenTek™ Fresh Protect™ Dental Guard	DenTek™ Ready-Fit™ Dental Guard	N/A
510(k) Number	TBD	K151149	N/A
Date Cleared	90 days from date of receipt by FDA	09/30/2015	N/A
Original applicant	Medtech Products Inc.	DenTek Oral Care, Inc.	N/A
REGULATORY CLASSIFICATION			
Regulatory Class	Unclassified	Unclassified	None

Name of Generic Device Type	Mouthguard, Over-the-Counter	Mouthguard, Over-the-Counter	None
Regulation	N/A	N/A	None
Product Code	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
DEVICE DESCRIPTION – SUBSTANTIAL EQUIVALENCE COMPARATORS			
Intended Use	Keep upper and lower teeth separated during sleep.	Keep upper and lower teeth separated during sleep.	None
OTC or Rx	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.	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.	None
Target Population	Adults 18 and older	Adults 18 and older	None
Duration of Use	1-3 days	1 day	Minor (testing conducted to confirm durability to 3 days, see Section 18 – Bench Testing)
Technological Characteristics	Flexible guard used as a barrier between teeth.	Flexible guard used as a barrier between teeth.	None
DEVICE DESCRIPTION – DESIGN FEATURES			
Material(s)	Ethylene/vinyl acetate copolymer)	Ethylene/methyl acrylate copolymer)	Minor (biocompatibility testing confirmed the DenTek™ Fresh Protect™ resin is appropriate for this intended use)
Design / Presentation	Full occlusion, ready-to-wear dental guard	Posterior occlusion, ready-to-wear dental guard	Minor (the full occlusion design is common in OTC dental guards)
Method of	Injection molding	Injection molding	None

Manufacture			
Method of Cleaning	Rinse with water before first use; if using for more than one night, wash between uses and inspect for signs of wear.	The device is meant to be discarded after one night's use. No instructions for cleaning are included.	Minor (the basic cleaning instruction provided are similar to those seen on other OTC dental guards)
Fit	One size fits all	One size fits all	None
Dimensions (L x W x H)	39.3 mm x 58 mm x 8.35 mm	38 mm x 39 mm x 19 mm	Minor (similar to the predicate)
Weight	0.79 grams (0.03 ounces)	1.13 grams (0.04 ounces)	Minor (similar to the predicate)
Accessories	None	None	None
Sterile Device	No	No	None
Use environment	Home	Home	None
Anatomical site of use	Oral Cavity	Oral Cavity	None

The table above identifies a few minor differences between the proposed device and the cited predicate. While the contact material for both devices is an ethylene-based copolymer, the exact resins are not identical; the appopriateness of the subject device's resin for use in a dental guard was demonstrated through biocompatability testing of the finished guards, which is provided in this application. Also, while both guards are labeled as "disposable" due to the short term intended use of each individual guard, the specific durations of use per the products' labeling differs: 1 day for the predicate and 1-3 days for the proposed device; this difference is minor because the DenTek™ Fresh Protect™ Dental Guard was shown adequately durable in a 3-day use simulation, the report for which is provided with this application. Another minor difference is that the predicate utilizes a posterior-occlusion design where the subject device – like many other OTC dental guards (refer to K091660 and K083400) – utilizes a full-occlusion design. Finally, though not identical, the measurements of the proposed guard are similar to the cited predicate (i.e., the resting bite radius is wider than the predicate because the predicate has a narrow strap between the bite pads that does not retain its in-use width) with a lower overall weight as intended to deliver an ultra-light guard.

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 do not raise different questions of safety or effectiveness and this application establishes that the device is as safe and effective as the predicates.

8. Non-Clinical Performance Data

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

- *Separation test*. Simulation study demonstrating the finished guard's ability to keep the teeth separated when the jaw is clenched.
- *Fit test*. Simulation study demonstrating the finished guard's ability to accommodate a range of arch widths without heating or adjustments.
- *Wear test*. Simulation study demonstrating the finished guard's durability for the intended use duration of 1-3 days.

The non-clinical testing of DenTek™ Fresh Protect™ Dental Guard demonstrates the device's performance in providing teeth separation, accommodating different mouth sizes, and lasting the expected use life, which supports its substantial equivalence to the cited predicate.

Additionally, the following tests for biocompatibility were conducted on both the DenTek™ Fresh Protect ™ 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 the DenTek™ Fresh Protect ™ Dental Guard is not cytotoxic, is not a contact skin sensitizer, and is 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™ Fresh Protect™ 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™ Fresh Protect™ Dental Guard, has the same intended use as the identified predicate device, the DenTek™ Ready-Fit™ Dental Guard (K151149), and employs the same basic technological characteristics; any differences between the proposed device and the predicates are minor and do not constitute different technological characteristics. The relevant information on biocompatibility and the performance testing confirm the DenTek™ Fresh Protect™ Dental Guard fulfills its intended use as safely and effectively as the legally marketed predicate device. The DenTek Fresh Protect™ Dental Guard is therefore substantially equivalent to the cited predicate.