August 23, 2019

Dental Choice Holdings, LLC
% E.J. Smith, Consultant
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K183315
Trade/Device Name: CustMBite Dental Guard
Regulatory Class: Unclassified
Product Code: OBR
Dated: July 24, 2019
Received: July 25, 2019

Dear E.J. Smith:

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,

for Srinivas Nandkumar, Ph.D.
Acting 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)*
K183315

Device Name
CustMBite Dental Guard

Indications for Use *(Describe)*
The CustMBite Dental Guard is an over-the-counter dental guard indicated for the protection against bruxism – the nighttime clenching and grinding of the teeth.

It is intended for use in the mouth at night to reduce damage to the teeth and to prevent the noise associated with teeth grinding.

The CustMBite Dental Guard is intended for individuals age 18 and older.

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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510(k) Summary

Submitter: Dental Choice Holdings, LLC

Address: 10100 Linn Station Road

Louisville, KY 40223

Contact Person: Ron Story

Vice President and Chief Information Officer

Telephone Number: 502-736-4600

Email: Ron.Story@deltadentalky.com

Summary Preparation Date: August 21, 2019

Device Description

Trade Name: CustMbite Dental Guard

Common Name: Mouthguard, over-the-counter

Regulatory Class:

Product Code: OBR

C.F.R. Section: Unclassified

Predicate Device:

Brand Name	510(k) Number
Oral-B plus Scope Outlast Nighttime Dental Guard	K113326

Device Description

CustMbite Dental Guard is an over-the-counter dental protector, which is used as a barrier between teeth for individuals who grind their teeth. The CustMbite Dental Guard is intended to be worn while sleeping (e.g., at night or while napping). Through the process of customization using a boil and bite technique, the device fits an individual mouth adapting to a given person's oral tissue contours.

Indications for Use

The CustMBite Dental Guard is an over-the-counter dental guard indicated for the protection against bruxism – the nighttime clenching and grinding of the teeth.

It is intended for use in the mouth at night to reduce damage to the teeth and to prevent the noise associated with teeth grinding.

The CustMBite Dental Guard is intended for individuals age 18 and older.

Substantial Equivalence Discussion

Parameters	Dental Choice Holdings, LLC CustMBite Dental Guard	Predicate Device Oral-B plus Scope Outlast Nighttime Dental Guard	Similarities and Differences
Product Code	OBR	OBR	Similar
Product Classification	Unclassified	Unclassified	Similar
Classification Name	Mouthguard, OTC	Mouthguard, OTC	Similar
Indications for Use	The CustMBite Dental Guard is an over-the-counter dental guard indicated for the protection against bruxism – the nighttime clenching and grinding of the teeth. It is intended for use in the mouth at night to reduce damage to the teeth and to prevent the noise associated with teeth grinding. The CustMBite Dental Guard is intended for individuals age 18 and older.	The Oral B plus Scope Outlast Nighttime Dental Guard is an over-the-counter dental guard indicated for the protection against bruxism – the nighttime clenching and grinding of the teeth. It is intended for use in the mouth at night to reduce damage to the teeth and to prevent the noise associated teeth grinding.	Similar
Intended Use	Aids in the reduction of tooth damage and noise due to bruxing and grinding	Aids in the reduction of tooth damage and noise due to bruxing and grinding	Similar
Anatomical Site and Type of Use	Intraoral, during sleep	Intraoral, during sleep	Similar

Parameters	Dental Choice Holdings, LLC CustMBite Dental Guard	Predicate Device Oral-B plus Scope Outlast Nighttime Dental Guard	Similarities and Differences
Materials	Propylene-based elastomer	Propylene-based elastomer and flavor	CustMBite does not contain a flavor
Molding Method	Heat & Bite Self-fit	Heat & Bite Self-fit	Similar
Fit	One size fits all via traditional heat and bite	One size fits all via traditional heat and bite	Similar
Reusable	Yes Single Patient	Yes Single Patient	Similar
Biocompatibility	Biocompatibility testing conducted in accordance ISO 10993-1	Biocompatibility testing conducted in accordance ISO 10993-1	Similar
Sterility	Non-sterile	Non-sterile	Similar
Compatibility with the Environment & Other Devices	Label warnings against use with certain other dental accessories	Label warnings against use with certain other dental accessories	Similar
Cleaning	Scrub with toothbrush, toothpaste and cold water	Scrub with toothbrush, toothpaste and cold water	Similar

Discussion of Technological Differences

a. Similarities:

The CustMbite Dental Guard has the following similarities to the predicate device: indications for use, intended use, anatomical site, material, molding method, customized fit., reusable, non-sterile, biocompatibility, cleaning and label warning.

b. Differences:
The predicate device offers flavors for the dental guard and the CustMbite Dental Guard offers no flavors.

Non-Clinical Testing

- ISO 14971 Second edition 2007-03-01 Medical devices - Application of risk management to medical devices
- ANSI AAMI ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ANSI/AAMI/ISO 10993-3:2014. Biological Evaluation of Medical Devices--Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
- ANSI/AAMI/ISO 10993-12: 2012. Biological Evaluation of Medical Devices Part 12: Sample Preparation and Reference Materials
- ISO 10993-10, 2010, Biological Evaluation of Medical Devices - Part 10: Tests for
- Irritation and Skin Sensitization
- ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and
- Calibration Laboratories
- ISO 10993-11, 2017, Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity

Clinical Testing

No clinical study was conducted.

Conclusion

Based upon similarities in indications for use, materials and principle of operation together with performance testing, we find that CustMbite Dental Guard to be substantially equivalent to Oral B plus Scope Outlast Nighttime Dental Guard (K113326).