November 6, 2023

Reazeal Corp
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
CHINA

Re: K231865
Trade/Device Name: Mouth Guard (ATG0603R)
Regulatory Class: Unclassified
Product Code: OBR
Dated: June 26, 2023
Received: June 26, 2023

Dear Ivy Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231865

Device Name
Mouth Guard (ATG0603R)

Indications for Use *(Describe)*
The Mouth 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.

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

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510(K) Summary

K231865
Prepared date: 11/03/2023

A. Applicant:

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B. Device:

Trade Name: Mouth Guard
Common Name: Over-the-Counter Dental Guard
Model: ATG0603R

Regulatory Information
Classification Name: Mouthguard, Over-the Counter
Regulation Number: N/A
Product Code: OBR
Device Class: Unclassified
Review Panel: Dental

C. Predicate device:

Predicate - K180933
DenTek Ultimate Dental Guard
Medtech Products Inc.

Reference device – K183315
CustMBite Dental Guard
Dental Choice Holdings, LLC

D. Indications for use of the device:

The Mouth 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.

E. Device Description:

The Mouth 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 a thermoplastic ethylene-vinyl acetate copolymer and is fitted by molding the bite pads to the user's teeth after the guard has been heated via submersion in boiled water. The fully occlusive guard is worn on the upper teeth, maintaining separation between the upper and lower teeth, thereby reducing the noise and damage associated with teeth grinding.

The Mouth Guard is intended for individuals age 18 and older. Thermoplastic can be molded to fit all sizes.

F. Comparison with predicate device

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Reference Device	Result
510K number	K231865	K180933	K183315	-
Model name	Mouth Guard	DenTek Ultimate Dental Guard	CustMBite Dental Guard	-
Classification	Unclassified	Unclassified	Unclassified	Same
Regulation	N/A	N/A	N/A	Same
Product code	OBR	OBR	OBR	Same
Indications for use	The Mouth 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 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 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.	Same with predicate device

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.	Same
OTC use	Yes	Yes	Yes	Same
Target population	Adults 18 and older	Adults 18 and older	Adults 18 and older	Same
Technological characteristics	Flexible, moldable guard used as a barrier between teeth.	Flexible, moldable guard used as a barrier between teeth.	Flexible, moldable guard used as a barrier between	Same
Material	Ethylene-vinyl acetate copolymer	Ethylene-vinyl acetate copolymer	Propylene-based elastomer	Same with predicate device.
Design	Full occlusion, boil-and-fit dental guard	Posterior occlusion, boil-and-fit dental guard	Full occlusion, boil-and-fit dental guard	Same with reference device.
Method of manufacture	Injection molding	Injection molding	Injection molding	Same
Method of cleaning	Scrub with toothbrush, liquid soap and cold water	Toothpaste or mouthwash, brush followed by cool water rinse.	Scrub with toothbrush, toothpaste and cold water	Similar
Fit	One size fits all via traditional heat and bite.	One size fits all via traditional heat and bite.	One size fits all via traditional heat and bite.	Same
Multiple use device	Yes	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Leaflet included	Yes	Yes	Yes	Same
Accessories	Storage case	Storage case	Storage case	Same
Use environment	Home	Home	Home	Same
Anatomical site of use	Oral cavity	Oral cavity	Oral cavity	Same

Discussion:

The table above identifies a few minor differences between the proposed device and the predicate device.

The design of the proposed device and reference device is full occlusion while the predicate device is posterior occlusion. Both of the two structures can achieve the intended use. This difference will not affect the safety and performance of the device.

The cleaning method of the two devices are slightly different, but both of them use toothbrush to scrub the devices and rinse with water. This difference will not affect the safety and effectiveness of

the proposed device.
The dimension of the proposed device is different with the predicate device, since it is a full occlusion design, which will not affect the safety and effectiveness of the proposed device.

G. Non-Clinical Test Conclusion

Bench testing has demonstrated that the device is in compliance with pertinent standards and specifications, the expectations of the dental community and the product labeling. Performance testing was performed to the proposed device including hardness, tear strength, impact and rebound, water absorption, impression test, separation test, stability test and durability test to demonstrate its effectiveness.
The non-clinical testing of Mouth Guard demonstrates the device's performance in providing including hardness, tear strength, impact and rebound, and water absorption, which supports its substantial equivalence to the predicate device.

Additionally, the following tests for biocompatibility were conducted on the Mouth Guard.

- Cytotoxicity
- Oral Mucosa Irritation
- Skin Sensitization
- Acute systemic toxicity
- Sub chronic systemic toxicity
- Genotoxicity

The results of the testing met the requirements of the study protocols and the material is considered non-toxic, non-sensitizing and is not an intracutaneous irritant. The results of the studies further support a determination of substantial equivalence to the predicate.

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K180933.