May 24, 2024

Xiamen Yizhou Imp. & Exp. Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, Shanghai 200122
CHINA

Re: K240810
Trade/Device Name: Anti Grinding Guard
Regulatory Class: Unclassified
Product Code: OBR
Dated: March 25, 2024
Received: March 25, 2024

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240810

Device Name

Anti Grinding Guard

Indications for Use *(Describe)*

The Anti Grinding Guard is a mouth guard intended to protect against grinding and clenching.

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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K240810

510(K) Summary

Prepared date: 2024-03-18

A. Applicant:

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B. Device:

Trade Name: Anti Grinding Guard
Common Name: Over-the-Counter Dental Guard
Model: YZ9003

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

C. Predicate device:

510(k) Number: K181099
Trade Name: Bright Guard
Manufacturer: Koncept Innovators, LLC.

D. Indications for use of the device:

The Anti Grinding Guard is a mouth guard intended to protect against grinding and clenching.

E. Device Description:

The Anti Grinding Guard is an over-the-counter (OTC), flexible and moldable one-piece dental

mouth guard, which is used as a barrier between teeth for individual s who grind their teeth. The anti Grinding Guard is intended to be worn while sleeping. The guard is constructed of 100% thermoplastic ethylene-vinyl acetate copolymer. When heated it forms to the individual's teeth. It is non-flavored and has no color additives. The mouth guard Is provided in one model/size, is reusable by a single individual at least eighteen (18) years of age and is supplied as non-sterile.

F. Comparison with predicate device

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Result
510K number	-	K181099	-
Model name	Anti Grinding Guard	Bright Guard	-
Classification	Unclassified	Unclassified	Same
Regulation	N/A	N/A	Same
Product code	OBR	OBR	Same
Indications for use	The Anti Grinding Guard is a mouth guard intended to protect against grinding and clenching.	Bright Guard is a mouth guard intended to protect against grinding and clenching.	Same
Intended use	Keep upper and lower teeth separated during sleep.	Keep upper and lower teeth separated during sleep.	Same
OTC use	Yes	Yes	Same
Target population	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.	Same
Molding Method	Boil and Bite Method (Heat & Bite Self-Fit)	Boil and Bite Method (Heat & Bite Self-Fit)	Same
Material	Ethylene-vinyl acetate copolymer	Ethylene-vinyl acetate copolymer	Same
Location of Use	Upper Arch Teeth	Upper Arch Teeth	Same
Method of manufacture	Injection molding	Injection molding	Same
Molding time	In hot water time: 15-20 seconds Mouth molding time: 20-25 seconds	In hot water time: 15-20 seconds Mouth molding time: 20-25 seconds	Same
Wear Time	Four (4) months wear time until replacement with new mouth guard.	Four (4) months wear time until replacement with new mouth guard.	Same

	Worn during sleeping for no more than twelve (12) hours per day.	Worn during sleeping for no more than twelve (12) hours per day.	
Sterility	Non-Sterile	Non-Sterile	Same
Anatomical site of use	Oral cavity	Oral cavity	Same
Biocompatibility	ISO 10993 complies	ISO 10993 complies	Same

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, water absorption and solubility testing, boiling/cooling water testing, impression test, separation test, and comparative wear test to demonstrate its effectiveness.

The non-clinical testing of Anti Grinding Guard demonstrates the device's performance in providing including hardness, water absorption and solubility testing, boiling/cooling water testing, impression test, separation test, and comparative wear test, 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 K181099.