April 17, 2024

Dimedikorea
℅ Kyung-Hwan Kim
Representative Consultant
SMB Korea
#606, #607, 7, Boramae-ro 5ga-gil, Donjak-gu
Seoul, 07071
SOUTH KOREA

Re: K232238
Trade/Device Name: Goyo Mouthpiece S
Regulatory Class: Unclassified
Product Code: OBR
Dated: March 14, 2024
Received: March 14, 2024

Dear Kyung-Hwan Kim:

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)*
K232238

Device Name
Goyo Mouthpiece S

Indications for Use *(Describe)*
The Goyo Mouthpiece S is indicated for use as a protection against bruxism or nighttime teeth grinding. The device is designed to reduce tooth damage and reduce the noise associated with bruxism or teeth 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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510(k) Summary

I. SUBMISSION SPONSOR

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Contact: Mr. Kyung-hwan Kim, Representative Consultant, QA
Email: info@smbkorea.com

III. DATE PREPARED

April 17, 2024

IV. DEVICE

Trade or Proprietary Name:	Goyo Mouthpiece S
Common or Usual Name:	Mouthguard, Over-The-Counter
Classification Name:	Unclassified, Pre-Amendment
Regulatory Class:	Unclassified
Product Code:	OBR
Classification Panel:	Dental

V. PREDICATE DEVICE

K133423, Rest Assured® Extra Comfort Nite Protector / Ranir, LLC

No reference devices were used in this submission.

VI. DEVICE DESCRIPTION

The mouthguard is an over-the-counter, flexible and moldable, one-piece dental mouthguard used as a barrier between the teeth for individuals who wish to prevent teeth grinding during sleep. The Goyo Mouthpiece S is made of ethylene vinyl acetate (EVA). The mouthguard material is conformable to wear and it can be self-fitting by heating the mouthguard in boiling water until it becomes malleable to fit on the upper teeth of the oral cavity. The Goyo Mouthpiece S comes in one model/size, is reusable by

a single individual eighteen (18) years of age or older, and is supplied non-sterile. The wearing period of the mouse guard is generally not more than twelve (12) hours a day and it is recommended to replace it with the new mouthguard in the one (1) month.

VII. INDICATION FOR USE

The Goyo Mouthpiece S is indicated for use as a protection against bruxism or nighttime teeth grinding. The device is designed to reduce tooth damage and reduce the noise associated with bruxism or teeth grinding.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The indications for use and mechanism of action of the subject device are identical to the predicate device and supports a determination of substantial equivalence.

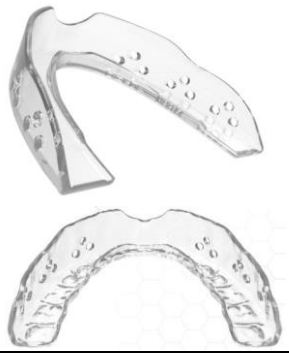
So that, the subject device performed testing as that of each predicate device. All test results for appearance, dimensions, Shore A hardness, tensile strength, tear strength, water sorption, and water solubility were similar to that of the predicate device.

The performance characteristics of the subject device are comparable to those of the predicate device for this particular indication and raise no new or different questions of safety and effectiveness.

Goyo Mouthpiece S has the same intended use/technical characteristics as the predicate, a soft, formable ethylene-vinyl acetate copolymer resin that, by way of the 'boil and bite' method, is fitted to an individual. Both the subject device and predicate device are molded to the upper arches providing a protective barrier between the individual's upper and lower teeth to prevent grinding.

It was concluded, therefore, that the technological differences do not raise different questions of safety and effectiveness.

	SUBJECT Device	**Primary PREDICATE Device (K133423)**	**Significant Difference**
Manufacturer	**DIMEDIKOREA**	**Ranir, LLC**	**–**
Trade Name/Device name	Goyo Mouthpiece S	Rest Assured® Extra Comfort Nite Protector	–
Regulation Description	Mouthguard, Over-The-Counter	Mouthguard, Over-The-Counter	–
Product Code	OBR	OBR	No difference.
Class	Unclassified	Unclassified	No difference.
Indications for Use	The Goyo Mouthpiece S is indicated for use as a protection against bruxism or nighttime teeth grinding. The device is designed to reduce tooth damage and reduce the noise associated with bruxism or teeth grinding.	The Rest Assured Extra Comfort Nite Protector Dental Protector is indicated for use for protection against bruxism or nighttime teeth grinding. The device is intended to reduce damage to teeth and to prevent the noise	No difference.

	SUBJECT Device	Primary PREDICATE Device (K133423)	Significant Difference
		associated with bruxing or grinding.	
OTC or Rx	OTC	OTC	No difference.
Materials of use	Ethylene Vinyl Acetate Copolymer [Elvax]	Ethylene Vinyl Acetate Copolymer [Elvax and Elvaloy]	Similarities: The subject device is manufactured using Elvax, whereas the predicate device is manufactured using a Elvax and Elvaloy. While these are not same formulation, each material is a known dental thermoplastic polymer with similar characteristics. Both subject device and the predicate are composed of flavorless, colorless thermoplastic elastomer resins designed for dental mouth guards and this difference do not affect the safety and effectiveness of subject device.
Molding method	Boil and Bite Method (Heat & Bite Self-Fit)	Boil and Bite Method (Heat & Bite Self-Fit)	No difference.
Method of Manufacturing	Injection molding	Injection molding	No difference.
Location of Use	Upper Arch Teeth	Upper Arch Teeth	No difference.
Molding Time	60 seconds in boiling water; 30 seconds to mold in mouth	60 seconds in boiling water; 30 seconds to mold in mouth	No difference.
Design			Similarities: The arch shape does not introduce any additional safety or efficacy concerns.
Dimension	W: Avg. 70.38mm; L: Avg. 47.32mm;	W: Avg. 66.6mm; L: Avg. 43.72mm;	Similarities: Although the subject device is larger in width, length, and height than the predicate device, it is designed to be thinner, making it easier to wear, and does not introduce any additional safety or

	SUBJECT Device	Primary PREDICATE Device (K133423)	Significant Difference
			efficacy concerns. Though not identical, the width measurement of the subject device is similar to the predicate device through demonstrated through mechanical testing of the finished guard.
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	No difference.
Tear Strength	Avg. 60.3 ± 4.13 N	Avg. 58.6 ± 4.92 N	-
Sterilization	Non-sterile	Non-sterile	No difference.

The table above shows some minor differences between the subjective device and the predicate device. But these differences do not affect the safety and effectiveness of subject device.

IX. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination:

Biocompatibility testing

The biocompatibility evaluation for the Goyo Mouthpiece S was conducted in accordance with the FDA Guidance entitled "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", SEPTEMBER 2020, as recognized by the FDA." The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Mechanical testing

Mechanical tests were performed to determine the appearance, dimensions, Shore A hardness, tensile strength, tear strength, water sorption, and water solubility of the mouthguard.

X. CLINICAL PERFORMANCE DATA

Clinical performance data demonstrating substantial equivalence have not been provided.

XI. CONCLUSIONS

The Goyo Mouthpiece S has been compared to predicate devices for safety and effectiveness. The information provided in this premarket notification demonstrates that the subject device has been determined to be substantially equivalent (SE) to the predicate devices.