June 4, 2024

Slow Wave Inc.
Sam Murray
Principal Consultant
26100 Countryside Dr.
Spicewood, Texas 78669

Re: K240463
Trade/Device Name: Slow Wave DS8 (SWDS802)
Regulatory Class: Unclassified
Product Code: MQC, OCO
Dated: February 16, 2024
Received: February 16, 2024

Dear Sam Murray:

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)*

K240463

Device Name

Slow Wave DS8 (SWDS802)

Indications for Use *(Describe)*

The Slow Wave DS8 is indicated for the treatment of sleep bruxism and as an aid in the treatment of associated tension/migraine type headaches in adults over the age of 18.

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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1. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

1.1. Submitter's Information

Name:	Slow Wave Inc.
Address:	26100 Countryside Dr. Spicewood, Texas 78669
Phone:	(210) 379-6269
Contact Person:	Wayne Wagner CEO
Preparation Date:	5 May 2024

1.2. Device Name

Trade Name:	Slow Wave DS8
Common Name:	Mouthguard
Classification Name:	Unclassified, Pre-amendment
Regulation	N/A
Regulatory Class:	N/A
Product Code	MQC, OCO

1.3. Legally Marketed Predicate Device

The legally marked predicate is the Luco Hybrid OSA Appliance (K160477)

1.4. Device Description

The Slow Wave DS8 is an intraoral appliance designed to safeguard teeth and restorations from the impacts of bruxism forces. It is a patient-specific device that consists of two trays worn on the maxilla and mandible conforming to the upper or lower teeth. This device acts as a physical divide between upper and lower tooth surfaces, preventing damage induced by bruxism activities such as grinding and clenching. Additionally, it eases discomfort associated with muscle tension and headaches. Multiple tray designs are available for this purpose, each offering distinct levels of functionality and suitability based on the patient's requirements. The device is manufactured using additive manufacturing, specifically on a Formlabs 3D Printer utilizing stereolithography (SLA) using biocompatible material.

1.4.1. Brief Written Description of the Device

The Slow Wave DS8 consists of two trays worn on the maxilla and mandible. The device is manufactured using additive manufacturing, specifically on a 3D stereolithography (SLA) printer made by Formlabs using Dental LT Clear V2 (K222061).

The trays are designed to be an exact custom fit from a digital intraoral scan of the user. A digital scan of the user's dentition using a 3Shape or comparable intraoral scanner, registering one's full impressions of the upper and lower teeth is used to create the trays. The trays are shaped like an arch where the covered portions are connected to each other by two palatal bands, one connecting the upper tray, and the other connecting the lower tray leaving the tips of the front teeth exposed.

Additionally, each design is manufactured to be patient specific, ensuring that the device can be precisely tailored to meet the unique requirements of each individual.

Beyond the Slow Wave DS8's preventive role, the device also addresses the discomfort associated with various bruxism-induced issues. By minimizing direct contact and impact, it contributes to the alleviation of muscle tension and headaches, providing a holistic solution to the multifaceted challenges posed by bruxism.

1.4.2. Materials of Use

The Slow Wave DS8 is additively manufactured by SLA (Formlabs Inc.) utilizing the medical-grade, acrylate-based photopolymer Dental LT Clear V2/BioMed Clear (Formlabs Inc.) (K222061).

1.5. Intended Use

The Slow Wave DS8 is intended for protection of teeth and restorations.

1.6. Indications for Use

The Slow Wave DS8 is indicated for the treatment of sleep bruxism and as an aid in the treatment of associated tension/migraine type headaches in adults over the age of 18.

1.7. Substantial Equivalence Discussion

The Slow Wave DS8 has the same intended use and technological characteristics as the predicate device. Differences in materials and manufacturing methods have been addressed through verification by analysis and do not raise questions of safety and effectiveness; therefore, the subject device is substantially equivalent to the predicate device. A comparison of the similarities and differences of the Slow Wave DS8 and cleared predicate are provided in Table 1.

Table 1: Predicate Comparison

Specification/ Characteristic	Subject Device	Predicate Device	Comparison	Reference Device	Reference Device
	Slow Wave DS8	**Luco Hybrid OSA Appliance (K160477)**		**Formlabs Dental LT Clear V2 (K222061)**	**Slow Wave DS8 (K191320)**
Classification	Unclassified	Unclassified	**Identical**	Unclassified	21 CFR 872.5570
Product Code	MQC, OCO	MQC, OCO	**Identical**	MQC, KMY, DYT	LQZ, LRK
Indications for Use	The Slow Wave DS8 is indicated for the treatment of sleep bruxism and as an aid in the treatment of associated tension/migraine type headaches in adults over the age of 18.	The Luco Hybrid OSA Appliance is indicated for: 1. A device to be used for the treatment of sleep bruxism and 2. As an aid in the treatment of associated tension/migraine type headaches in adults.	**Identical**	Dental Clear LT V2 Resin when utilized to print dental or orthodontic appliances such as occlusal splints, night guards, or mouth guards is indicated to treat patients diagnosed with Temporomandibular Joint Disorders (TMD) and/or Bruxism, respectively	Intended to reduce or alleviate snoring, mild to moderate Obstructive Sleep Apnea (OSA) while sleeping in adults.
Prescription Status	Prescription Only	Prescription Only	**Identical**	Prescription Only	Prescription Only
Target Population	Adults	Adults	**Identical**	Adults	Adults
Use of Device	Removable intraoral device. Single patient multiple use.	Removable intraoral device. Single patient multiple use.	**Identical**	3D Printing Resin	Removable intraoral device. Single patient multiple use.

Specification/ Characteristic	Subject Device	Predicate Device	Comparison	Reference Device	Reference Device
	Slow Wave DS8	**Luco Hybrid OSA Appliance (K160477)**		**Formlabs Dental LT Clear V2 (K222061)**	**Slow Wave DS8 (K191320)**
Principle of Operation	The Slow Wave DS8 is a personalized appliance designed to protect against bruxism forces and relief from associated discomfort. It creates a physical separation between upper and lower teeth, preventing damage from grinding and clenching. The appliance addresses muscle tension and headaches related to bruxism. Customized through intraoral scans, it ensures an optimal fit and functionality.	This patient-specific device functions as a protective barrier for teeth and restorations by creating physical separation between upper and lower tooth surfaces preventing tooth damage caused by bruxism (like grinding and clenching) and alleviating muscle and tension headache pains.	**Substantially equivalent**	Light-curable polymer-based resin designed for the fabrication of biocompatible, long-term use, removable dental and orthodontic appliances by additive manufacturing	Adjustment of the relative position of the ramps guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position. Traction-based mandibular repositioning device, allows nasal and/or oral breathing
Features	• Mandibular and Maxillary arch • Vertical opening	• Mandibular and Maxillary arch • Vertical opening	**Identical**	N/A	• Mandibular and Maxillary arch • Vertical opening
Material Properties	Compliant with ISO 20795-2	Unknown	**Substantially Equivalent**	Compliant with ISO 20795-2	Compliant with ISO 20795-2
Materials	Formlabs Dental LT Clear V2	Methyl methacrylate, chrome cobalt, medical grade stainless steel	**Substantially Equivalent**	Formlabs Dental LT Clear V2	Formlabs Dental LT Clear V2
Manufacturing Method	CAD/CAM 3D printing (additive)	Casting	**Substantially Equivalent**	CAD/CAM 3D printing (additive)	CAD/CAM 3D printing (additive)
Provided Sterile	No	No	**Identical**	No	No

1.7.1. Statement on Substantial Equivalence

The proposed device and predicate device are both oral appliances devices with the same intended purpose. The proposed device and predicate share the same fundamental features. They are patient-specific dental appliances with a mandibular and maxillary arch which covers the top and bottom teeth allowing for a vertical opening. They are non-sterile appliances used intraorally by a single patient.

1.8. Performance Data

Performance requirements were determined through an assessment of the physical properties of the device. The assessment of the Slow Wave DS8's ability to achieve its intended use concluded that the appliance meets the same specifications as both reference devices and is substantially equivalent to the primary predicate.

1.8.1. Clinical Studies

Clinical testing was not necessary for the demonstration of substantial equivalence.

1.9. Conclusions

The Slow Wave DS8 has the same intended use and technological characteristics as the predicate device. Differences in materials and manufacturing methods have been addressed through verification by analysis and do not raise questions of safety and effectiveness; therefore, the subject device is substantially equivalent to the predicate device.