October 2, 2020

Slow Wave, Inc.
Wayne Wagner
President / Owner
26100 Countryside Dr.
Spicewood, Texas 78669

Re: K191320
Trade/Device Name: Slow Wave DS8
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: LQZ, LRK
Dated: September 17, 2020
Received: September 18, 2020

Dear Wayne Wagner:

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 “Nandu” Nandkumar, Ph.D.
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)*
K191320

Device Name
Slow Wave DS8

Indications for Use *(Describe)*
Intended to reduce or alleviate snoring, mild to moderate Obstructive Sleep Apnea (OSA) while sleeping in adults.

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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510k Summary

510k Owner:	Slow Wave, Inc.
510k Owner Address:	26100 Countryside Dr., Spicewood, TX 78669, USA
Owner:	Wayne R Wagner
Contact:	Valentina Ovalle
Phone:	(210)-379-6269
Email:	tina@wagnerfamily.cc
Submission Correspondent:	Shree Koushik Ph.D. RAC BDRA Consulting LLC 1 Clearwater Court, Damascus, MD 20872
Phone:	301-922-7231
Email:	shree@bdraqa.com
Date Prepared:	October 1, 2020
Device Trade Name:	Slow Wave DS8
510k Number:	K191320
Primary Predicate:	
Device Name:	Panthera D-SAD
Classification Name:	Intraoral Devices for Snoring and Intraoral Devices For Snoring And Obstructive Sleep Apnea
510k Number:	K142344
Classification:	Class II
Regulation Number:	21 CFR 872.5570
Product Code:	LQZ, LRK
Review Panel:	Dental
Reference Device:	
Device Name:	The NightBlocks Appliance
Classification Name:	Intraoral Devices for Snoring and Intraoral Devices For Snoring And Obstructive Sleep Apnea
510k Number:	K192581
Classification:	Class II
Regulation Number:	21 CFR 872.5570
Product Code:	LQZ, LRK
Review Panel:	Dental

Intended Use/Indications for Use:	Slow Wave DS8 device is intended to reduce or alleviate snoring, mild to moderate Obstructive Sleep Apnea while sleeping in adults.
Device Description:	DS8 consists of two trays worn on the maxilla and mandible. The device is manufactured at Slow Wave facilities using additive manufacturing, specifically on a Formlabs 3D Printer utilizing stereolithography (SLA) using biocompatible material. The trays are designed to be an exact custom fit by a trained dental technician, using a 3Shape intraoral scanning device, or comparable intraoral scanner such as the iTero, or Cerec, registering one's full impressions of the upper teeth, lower teeth. A bite scan registration with a gap (typically 8 mm), which is a crucial design feature. The gap results from the design of the lower and upper trays. The upper and lower trays, the molars, premolars, and canines, are covered by the device. However, the lateral or central incisors are not covered, which effectively leaves eight teeth (four maxillary incisors and four mandibular incisors) uncovered. The trays are shaped like arch because the covered portion of the device is connected to each other by two palatal bands one connecting the upper left and upper tray, and the other connecting the lower tray. Additionally, the trays are built with ramps that guide the mandible forward and downward, thus maintaining advancement, enlarging the airway, allowing more room for the tongue to migrate forward naturally. The vertical opening of the jaw is not fixed in a single position. DS8 is a traction-based mandibular repositioning device that allows nasal and/or oral breathing.
Operating Principle:	The Slow Wave DS8 (K191320), is a mandibular repositioning device that acts to increase the users' pharyngeal space and improves their ability to exchange air during sleep. The device consists of

two separate trays worn on the maxilla and mandible, which allow the user to:

- Open and close their jaw when asleep
- Provide full lateral movement of the mandible

Move the tongue forward to enhance air exchange during sleep.

The DS8 trays worn on the maxilla and mandible with integrally formed molar extensions forming forward-leaning left and right ramps configured so that when the apparatus is in a users' mouth, the ramps create a tendency for the lower tray, lower dentition and mandible to move in a normal downward position as they move back toward the users' throat, keeping users' airway open by maintaining an anterior Gap making more space for the tongue and helps to alleviate snoring and mild to moderate obstructive sleep apnea. Figure 1 and 2 provide pictorial representation of a blocked airway and DS8 mediated clearing of the blocked airway.

Biocompatibility:

ISO 7405 and ISO 10993 compliant biocompatibility assessment on 3D printed material using Dental LT Clear V2 and BioMed Clear materials was completed by Formlabs. Based on the risk assessment Formlabs conducted, Cytotoxicity, Irritation, Sensitivity, acute systemic toxicity, subchronic systemic toxicity, genotoxicity and implantation studies. All tests passed and the material was deemed to be biocompatible for its intended use.

Animal or Human testing:

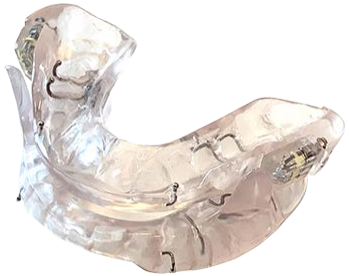
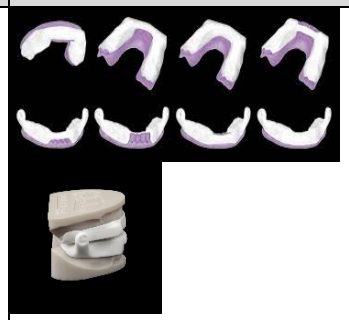
No Animal or Human testing was conducted on DS8 device.

Substantial Equivalence:

Slow Wave DS8 has the same intended use as the predicate devices. Additionally, the differences in technological characteristics do not raise new questions of safety and effectiveness. Therefore, based on the substantial equivalence evaluation,

Slow Wave concludes that the Slow Wave DS8 is substantially equivalent to Panthera D-SAD.

Substantial Equivalence Table:

Feature	**Slow Wave DS8 (K191320) Subject device**	**The NightBlocks Appliance (K192581) Primary Predicate**	**Panthera D-SAD (K143244) Reference device**	**Comparisons**
Picture of the device				**Subjected Similar to its Predicate**
Indications for Use	Intended to reduce or alleviate snoring, mild to moderate Obstructive Sleep Apnea while sleeping in adults.	Intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The NightBlocks™ Appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The customized appliance is inserted and removed by the patient and adjusted by the prescribing dentist.	Intended to reduce or alleviate snoring, mild to moderate Obstructive Sleep Apnea while sleeping in adults.	
Product Codes	LQZ, LRK	LQZ, LRK	LRK	**Same to all**
Regulation	21CFR 872.5570	21CFR 872.5570	21CFR 872.5570	**Same to all**
Common Name	Intraoral device for snoring and mild to moderate Obstructive Sleep Apnea	Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea	Intraoral device for snoring and mild to moderate Obstructive Sleep Apnea	**Same to all**

Feature	Slow Wave DS8 (K191320) Subject device	The NightBlocks Appliance (K192581) Primary Predicate	Panthera D-SAD (K143244) Reference device	Comparisons
Classification	Class II	Class II	Class II	**Same to all**
Use of Device	Removable intraoral device. Single patient multiple use. Prescription use only.	Removable intraoral device. Single patient multiple use. Prescription use only.	Removable intraoral device. Single patient multiple use. Prescription use only.	**Same to all**
Target Population	Adult Patients	Adult Patients	Adult Patients	**Same to all**
Principle of operation	Adjustment of the relative position of the ramps guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of jaw is not fixed in a single position. Traction-based mandibular repositioning device, allows nasal and/or oral breathing	Mandibular Repositioning with custom fitted acrylic upper and lower components. This advances the mandible anteriorly to enlarge the airway. Expansion mechanism placed on buccal portions for unobstructed airway passage.	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of jaw is not fixed in a single position. Traction-based mandibular repositioning device, allows nasal and/or oral breathing	**Same to all**
Mandibular Advancement Range	Up to 15 mm at 1 mm increments.	Mandible can be advanced with two buccal expansion screws up to 6mm.	Up to 15 mm at 1 mm increments.	**Same to all**
Occlusion trays	It covers part of the occlusal surface of upper and lower devices then covering inside gum area at upper and lower Incisors	Information not available	It covers part of the occlusal surface of upper and lower devices then covering inside gum area at upper and lower Incisors	**Same to all**
Fixed/Removable	Removable	Removable	Removable	**Same to all**
Supplied sterile / non sterile	Non sterile	Non Sterile	Non sterile	**Same to all**

Feature	Slow Wave DS8 (K191320) Subject device	The NightBlocks Appliance (K192581) Primary Predicate	Panthera D-SAD (K143244) Reference device	Comparisons
Single Use / reusable	Reusable	Reusable	Reusable	**Same to all**
Prescription / Over the Counter	Prescription	Prescription	Prescription	**Same to all**
Cleaning and Maintenance	Clean daily in lukewarm water with a soft toothbrush. Rinse, dry and store in case provided. Twice a week use antibacterial orthodontic cleansing solution that are chlorine-free	Information not available online or from FDA 510k summary. It is safe to assume some form of cleaning is advised.	Clean daily in lukewarm water with a soft toothbrush. Rinse, dry and store in case provided. Twice a week use antibacterial orthodontic cleansing solution that are chlorine-free	**Same to all**

Conclusion:	Slow Wave DS8 has the same intended use as the predicate device. Additionally, the differences in technological characteristics do not raise new questions of safety and effectiveness. Therefore, based on the substantial equivalence evaluation, Slow Wave concludes that the Slow Wave DS8 is substantially equivalent to Panthera D-SAD and the NighBlocks Appliance.