September 3, 2020

Diamond Orthotic Laboratory
% Dave Yungvurt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K202499
Trade/Device Name: Diamond Digital Sleep Orthotic (DDSO)
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: LRK
Dated: August 27, 2020
Received: August 31, 2020

Dear Dave Yungvurt:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202499

Device Name
Diamond Digital Sleep Orthotic

Indications for Use *(Describe)*
The Diamond Digital Sleep Orthotic (DDSO) is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) 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.

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Section 5 – 510(k) Summary K202499

[As required by 21 CFR 807.92]

Date Prepared:	August 14, 2020
Submitter:	Matt Rago Diamond Orthotic Laboratory 7859 El Cajon Blvd. La Mesa, CA 91942 Tel: (619) 724-6400 Fax: (619) 724.6401
Official Contact:	Matt Rago Director of Operations matt@diamondorthoticlab.com Tel: (619) 724-6400 Fax: (619) 724-6401
Device Trade Name:	**Diamond Digital Sleep Orthotic**
Device Common Name:	Mandibular Repositioning
Device Classification:	21 CFR 872.5570 (Class II)
Classification Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.
Product code:	LRK
Predicate Device:	The Panthera Anti-Snoring Device (K143244)
Reference Device:	The Panthera Anti-Snoring X3 Device (K171576)

5.1 Device Description

The Diamond Digital Sleep Orthotic (DDSO) is a removable intraoral device intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults. The device functions as a mandibular repositioner, maintaining the lower jaw in a forward, (protrusive) position during sleep. This mechanical protrusion acts to increase the patient's pharyngeal space and decrease air turbulence, therefore improving their ability to exchange air during sleep.

The DDSO is a patient-matched prescription medical device, indicated for use during sleep to treat patients who snore and/or have mild to moderate obstructive sleep apnea. The design consists of two splints that fit independently over the upper and lower teeth and engage by means of an adjustable mechanism. This mechanism enables the practitioner to set the amount of mandibular advancement at the time of fitting the device.

The amount of titration (mandibular protrusion) ranges from 0 to +5mm in 1.0 mm increments.

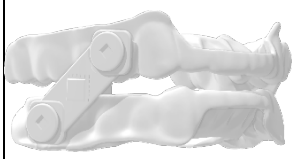
5.2 Indications for Use:

The Diamond Digital Sleep Orthotic (DDSO) is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

5.3 Technological Characteristics

The following table displays the differences and similarities between the new DDSO device, one other previously marketed (predicate) device: The Panthera Anti-Snoring Device and one previously marketed reference device: The Panthera Anti-Snoring X3 Device: used to support that the difference in advancement range(s) do not raise new questions of safety or effectiveness. Equivalence is based on, but not limited to similarities in: indication for use, materials of construction, technology, design, operating principles, patient contact, etc.

Table 2:510(K) Summary Table

		
		Predicate Device
Substantial Equivalence Topic	**Diamond Digital Sleep Orthotic (DDSO)**	**The Panthera Anti-Snoring Device (K143244)**
Intended as intraoral device	Yes	Yes
Regulation Description	Intraoral devices for snoring and obstructive sleep apnea (OSA)	Intraoral devices for snoring and obstructive sleep apnea (OSA)
Product Code	LRK	LRK
Classification	Class II	Class II
Patient Population	Adult	Adult
Environments of Use	Home, Dental/Medical offices, Sleep laboratories	Home, Dental/Medical offices, Sleep laboratories
Single Use/Reusable	Reusable	Reusable
Used and cleaned daily	Yes	Yes
Prescription/OTC	Prescription only	Prescription only

Indications for Use	To reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	To reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.
Custom fit upper and lower tray	Yes	Yes
Can be refit or adjusted	Yes	Yes
Allows lateral and vertical movements	Yes	Yes
Fixed/Removable	Removable	Removable
Materials of construction:	Made of PA2200 Nylon (polyamide type 12), Supplied by EOS GmbH. ▪ Highly resilient and durable ▪ Flexible ▪ Biocompatible Entire device and components are made with PA 2200 Nylon	Made of PA2200 Nylon (polyamide type 12), Supplied by EOS GmbH. ▪ Highly resilient and durable ▪ Flexible ▪ Biocompatible Entire device and components are made with PA 2200 Nylon
Design Process:	▪ Use the computer-aided design (CAD) and computer-aided manufacturing (CAM). ▪ Selective laser sintering	▪ Use the computer-aided design (CAD) and computer-aided manufacturing (CAM). ▪ Selective laser sintering
Device Design:	▪ Two customized splints that fit separately over the upper and lower teeth inside the mouth. The upper and lower splint contains retention mechanism allow the splints to engage by means of interlocking bands on the buccal surface of the device.	▪ Two customized splints that fit separately over the upper and lower teeth inside the mouth. The upper and lower splint contains retention mechanism that allow the splints to engage by means of interlocking rods on the buccal surface of the device.
Principle of operation	▪ Mandibular advancement	▪ Mandibular advancement
Means of Mandibular Advancement	• Adjustment of relative position of the splints guide the mandible forward and maintain advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position. ▪ Traction-based mandibular repositioning device, allows for nasal and/or oral breathing	• Adjustment of relative position of the splints guide the mandible forward and maintain advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position. ▪ Traction-based mandibular repositioning device, allows for nasal and/or oral breathing

Advancement Mechanism/Adjustment	Adjusted via use of interchangeable bands on the sides of the splints. The shorter the band, the further the mandible is advanced. The bands engage via buttons/retention hooks on the buccal surface of the device. Bands are available in 1 mm increments. The practitioner can select a shorter band until optimal advancement is achieved.	Adjusted via use of interchangeable rods on the sides of the splints. The shorter the rod, the further the mandible is advanced. The rods engage via triangular protrusions that interlock the rod on the buccal surface of the device. Rods are available in 1 mm increments. The practitioner can select a Shorter rod until optimal advancement is achieved.
Mandibular Advancement Range	0 to 5mm in 1mm increments (Up to 5mm advancement)	0 to 15mm in 1mm increments (Up to 15mm advancement)
Supplied sterile/non sterile	Non-sterile	Non-sterile
Cleaning & Maintenance	Clean daily in lukewarm water with a soft bristled toothbrush. Rinse, dry, and store in case provided. Use antibacterial orthodontic cleansing solution that are chlorine free.	Clean daily in lukewarm water with a soft bristled toothbrush. Rinse, dry, and store in case provided. Use antibacterial orthodontic cleansing solution that are chlorine free.
Biocompatibility	• ISO-10993-1 • ISO-10993-5 • ISO-10993-10 • ISO-10993-12 • ISO-10993-17 • ISO-10993-18	Information could not be verified. Statement in K143244 “The device is biocompatible, based on the similarity of the materials of construction to the predicate device (Narval CC) marketed by ResMed”

5.4 Performance Testing: Non-Clinical

Internal verification and validation testing demonstrate that product specifications are met and equivalent in design, performance, and technological characteristics. As part of demonstrating substantial equivalence, Diamond Orthotic Laboratory completed a performance evaluation to assess the composition of raw materials and the manufacturing process of the device. Additional testing evaluated the physical properties, mechanical strength and comparative analysis of the subject device (DDSO) and the predicate device in parallel. Fatigue testing was conducted on the new device to assess the assembly and critical functioning components. A final custom load test was performed on the new device and the predicate and assessed in parallel.

Bench testing was conducted to determine the critical process parameters for Selective Laser Sintering in accordance with the FDA Guidance Document: *Technical Considerations for Additive Manufactured Medical Devices* and following standards: *ASTM D638, ASTM D790 and ISO/ASTM 52921-13.* Results demonstrate that design outputs meet the design inputs and specifications for Diamond's additive manufacturing processes and control. The conclusions drawn from nonclinical tests performed on the DDSO and the predicate device in parallel demonstrate that the subject device is as safe, as effective, and has sufficient mechanical strength for its intended clinical use and therefore can be considered substantially equivalent to the predicate: Panthera Anti-Snoring Device.

5.5 Biocompatibility Testing

Diamond Orthotic Laboratory completed a biological evaluation plan to assess the biocompatibility of materials and the material composition used for manufacturing the device. The purpose of this assessment was to ensure that biocompatibility had been established for the proposed device referencing the following standards: *ISO 14971 Medical Devices - Applications Of Risk Management to Medical Devices* and *ISO 10993-1, 10993-5, 10993-10, 10993-12, 10993-17, and 10993-18.* Comparative chemistry consisted of extractables and leachable extract and a toxicological risk assessment of the compounds identified. Results validate Diamond's control of Additive Manufacturing parameters and validates reprocessing instructions that ensure that the device can be used safely and for the purpose for which it is intended. The toxicology report demonstrates that the Diamond Digital Sleep Orthotic is toxicologically equivalent to the predicate device and therefore as safe and as effective for its intended use. This conclusion is based on comparative analytics and use of the same raw materials of construction and the same manufacturing process as the predicate device. The Diamond Digital Sleep Orthotic (DDSO) is as safe and as effective as the predicate device and therefore, substantially equivalent for its intended use.

5.6 Clinical Testing

Per FDA guidance document: *"Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Guidance for Industry and FDA,"* human clinical studies

were not deemed necessary. The DDSO does not:

1. Use designs dissimilar from the predicate device and other previously cleared devices under a 510 (k).
2. Use new technologies different from legally marketed intraoral mandibular repositioning devices for treating snoring and mild to moderate obstructive sleep apnea.
3. Deviate or make changes in the indications for use identified in the predicate device.

5.7 RISKS

Diamond Orthotic Laboratory performed a risk analysis and evaluated the materials of construction and the design process for all hazards in accordance with *ISO 14971:Medical devices - Application of risk management to medical devices..* Verification and validation have been carried out in accordance with FDA guidelines for all processes required in the design, manufacturing, and final processing of additive manufactured devices. All testing methods and results support that all software specifications have met the acceptance criteria of each module and interaction of processes. Validation activities include, but are not limited to: usability studies, finite element analysis validated through mechanical testing, performance testing and several comparative analysis in parallel with the predicate device. A process in Diamonds quality system developed in accordance with *ISO:14971* is used to identify hazards and hazardous situations, estimate and evaluate the risks subject to worst-case scenarios, and mitigate the risks including overall residual risk. With respect to perceivable conditions in which the device would be subjected to a worst-case environmental or human error scenario, Diamond Orthotic Laboratory believes the outcomes of these risks are considered acceptable within the context of *ISO 14971:Medical devices - Application of risk management to medical devices*.

The function of mandibular advancement devices requires that the prescribing dentist be cognizant of the potential for soreness, soft tissue soreness, and dentition complications (soreness, motion,

loosening) by mandibular advancement. Management of these risks is achieved by advising the patient and dentist on proper care, adjustments and use in IFU and practitioner guides. In early stages while the patent acclimates to the device, examination of the fit and its performance, must be performed in the dental office by the prescribing dentist. The contraindications, warnings, precautions, storage directions, prescription preparation instructions, fitting and adjustment directions are written to avoid potential problems from arising or persisting with the dentition, tissue, or joints, caused by the OSA devices. Since no new risks are introduced with the new device that are not present in the predicate device it can be concluded that the DDSO device is as safe and as effective for its intended use and therefore substantially equivalent the predicate device. A detailed FMEA risk analysis can be found in A*ppendix I.*

5.8 Substantive Equivalence

The new device, the Diamond Digital Sleep Orthotic (DDSO) is considered to be substantially equivalent to the predicate device with respect to: the same intended use and indications for use, similar technological characteristics, fabrication process, and methods of operation. All comparative differences between the new device and the predicate device are identified and do not raise new questions of safety and effectiveness. The reference device (K171576) supports the performance over the advancement range and provides rationale to support why the difference in adjustable range does not affect substantial equivalence. All methods for evaluation are acceptable and demonstrates that the DDSO device is as safe and effective and does not raise different questions of safety and effectiveness than the legally marketed predicate device: the Panthera Anti-Snoring device marketed by Panthera Dental, Inc.