May 9, 2024

Good Sleep Co Pte Ltd.
% Na Zhang
Project Manager
evo820, LLC
1 Bay Street
Rancho Mission Viejo, California 92694

Re: K232025
Trade/Device Name: Hushd Pro Avera
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: June 27, 2023
Received: July 7, 2023

Dear Na Zhang:

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
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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)*

K232025

Device Name

Hushd Pro Avera

Indications for Use *(Describe)*

The Hushd Pro Avera device 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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K232025

510(k) Summary

SUBMITTER

Date Prepared: **May 7, 2023**

Submitter: Good Sleep Co Pte Ltd.

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Singapore

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DEVICE

Trade/Proprietary Name:	Hushd Pro Avera
Classification Name :	Device Anti-Snoring
Common Name :	Intraoral device for snoring and mild to moderate obstructive sleep apnea
Classification Regulations:	21CFR 872.5570
Product Code:	LRK
Device Classification:	Class II
Classification Panel:	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PRIDICATE DEVICE

Predicate Device:	K143244	The Panthera Anti-Snoring Device	Panthera Dental, Inc.
Reference Device:	K133683	MicrO2 Obstructive Sleep Apnea Device	MicroDental laboratories
	K220330	Soundly Mandibular Advancement Device	Greystone IP Ltd
	K171576	Panthera Anti-Snoring X3 Device	Panthera Dental, Inc.

DEVICE DESCRIPTION

The Hushd Pro Avera device series are a set of removable intraoral patient specific device used for treating snoring and mild to moderate obstructive sleep apnea. The device consists of number of custom made maxillary and mandibular splints fit over the upper and lower teeth, when interfaced together, functions as a mandibular repositioner holding the mandible forward during sleep thus preventing the togue and soft tissues of the throat from collapsing into the airway.

The Hushd Pro Avera device series are patient-specific devices, consisting of one or more maxillary device(s) and one or more mandibular device(s) that mates together. The sequential devices are CAD/CAM designed and manufactured according to the requested mandibular advancements position prescribed by the dentist or physician to provide a selection of gentle advancements according to patient comfort and need. As such, prescribed advancements can be achieved by simply removing current maxillary or mandibular device and inserting the next maxillary or mandibular device in the advancements series. The maximum protrusion of the device is 10mm.The Hushd Pro Avera device does not have any adjustment mechanisms to modify or maintain the mandibular position such as pistons, screws, straps or repositioning elastics.

INDICATIONS FOR USE

The Hushd Pro Avera device is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

COMPARISON OF TECHNOLOGICAL WITH THE PREDICATE DEVICE

The subject device is substantial equivalent in intended use and technological characteristics to the predicate devices shown above. Below is a summary table comparing the subject device with the primary predicate and reference devices.

Features	Submission Device	Predicate Device	Reference Device	Reference Device	Reference Device
Manufacture	Good Sleep Co Pte Ltd.	Panthera Dental, Inc.	MicroDental laboratories	Greystone IP Ltd	Panthera Dental Inc.
Trade Name	Hushd Pro Avera	The Panthera Anti-Snoring Device	MicrO2 Obstructive Sleep Apnea Device	Soundly Mandibular Advancement Device	Panthera Anti-Snoring X3 Device
510(k) Number	K232025	K143244	K133683	K220330	K171576
Regulation Number	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570
Classifications	Class II	Class II	Class II	Class II	Class II
Product Code	LRK	LRK	LRK	LRK, LQZ	LRK
Indications for Use	The Hushd Pro Avera device is	The Panthera Anti-Snoring	The MICRODENTAL	The Soundly Mandibular	The Panthera Anti-Snoring X3 Device

	intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	device is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	, Inc, micrO2 device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Advancement Device is intended to reduce or alleviate snoring and mild to moderate Obstructive Sleep Apnea(OSA) whilst sleeping in adults.	is intended to reduce or alleviate snoring and mild to moderate obstructive sleep Apnea(OSA) in adults.
Principle of Operation	Mandibular Repositioners, Repositions the lower jaw forward to increase the patency of the airway	Mandibular Repositioners, Repositions the lower jaw forward to increase the patency of the airway	Mandibular Repositioners, Repositions the lower jaw forward to increase the patency of the airway	Mandibular Repositioners, Repositions the lower jaw forward to increase the patency of the airway	Mandibular Repositioners, Repositions the lower jaw forward to increase the patency of the airway
Adjustment mechanism	Advancements can be achieved by simply removing the current upper or lower device and inserting the next upper or lower device in the mandibular advancing series.	Adjusted via the use of interlocking rods placed on each side of the mandible splint. The shorter the rod, the further mandible is advanced. The dentist can select a shorter connecting rod until optimal advancement is achieved	Advancements can be achieved by simply removing the current upper or lower device and inserting the next upper or lower device in the mandibular advancing series.	User choose which of the 3 lower splints to wear-self titration	Adjusted via the adjustable clip assembly placed on each side of the maxillary splint. The longer the stop-clip is, the further the mandible is advanced. The dentist can select a longer stop-clip until optimal advancement is achieved.
Mandibular advancement range	Up to 10mm 50-90% of the patient's maximum comfortable mandibular advancement at 1mm increment	Up to 15mm at 1mm increment	Up to 6.0mm	3 positions at 40%,60% & 70% of the patient's maximum comfortable mandibular advancement Maximum advancement is 12mm	Up to 5mm at 1mm increments
Material	Made from polymers (polyamide type 12), Supplied by EOS	Made from polymers (polyamide type 12), Supplied by EOS	Hard PMMA material	Form labs Dental LT Clear V2	Made from polymers(polyamide type12), supplied by EOS.
Biocompatible	Yes	Yes	Yes	Yes	Yes
Rx or OTC	Rx	Rx	Rx	Rx	Rx
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Target Population	Adults	Adults	Adults	Adults	Adults
Design	Two customized intra oral splints	Two customized intra oral splints	Two customized intra oral splints	Two customized intra oral splints	Two customized splints that fit

	that fit separately over the upper and lower teeth. These separate maxillary and mandible splints are designed with twin-mated posts, when interface together , functioning as mandible repositioner holding the mandible forward during sleep	that fit separately over the upper and lower teeth. The mandible splint contains a triangular protrusion allowing the splints to engage by means of interlocking rods on the sides .	that fit separately over the upper and lower teeth. These separate maxillary and mandible splints are designed with twin-mated posts, when interface together , functioning as mandible repositioner holding the mandible forward during sleep	that fit separately over the upper and lower teeth. The mandibular advancement is achieved by the interlocking of opposing wedge faces on the upper and lower jaw position, There are no locking side arms, so the splints can be disengaged by a small forward and downward movement of lower jaw. The upper splint is supplied with 3 sizes of mandibular advancement , tied to the patient's maximum mandibular advancement.	separately over the upper and lower teeth inside the mouth. The mandible splint contains wing protrusions that interface with the incline blocks built into the buccal of the maxillary splint.
Manufacture Technology	Use the computer -aided design (CAD) and Computer-aided manufacturing(CAM) Use CAD that enables a high degree of customization according the physician or dentists prescription to accommodate the complex dental anatomy of individual patients. The CAM and selective laser sintering guarantees precision , accuracy and	Use the computer -aided design (CAD) and Computer-aided manufacturing(CAM) Use CAD that enables a high degree of customization according the physician or dentists prescription to accommodate the complex dental anatomy of individual patients. The CAM and selective laser sintering guarantees precision , accuracy and	Use the computer -aided design (CAD) and Computer-aided manufacturing(CAM)	Use the computer -aided design (CAD) and Computer-aided manufacturing(CAM)	Uses computer-aided(CAD) and computer-aided manufacturing(CAM). Uses CAD that enables a high degree of customization according to the physician or dentist prescription. The CAM and selective laser sintering guarantee precision, accuracy and consistency of each patient.

	consistency for each patient	consistency for each patient			

Compared to the predicate device , the Hushd Pro Avera has the same intended use/Indications for use , principle of operation , fabricated by using the same material and a similar manufacturing technology except its adjustment mechanism , however the same adjustment mechanism was adopted by the reference device. The slight difference in twin-mate posts design between the subject device and reference device does not affect the equivalence in function and intended use of the devices. Therefore, the subject device is considered to be substantially equivalent to the predicate device and/or the reference device based on a comparison of intended use and technological characteristics.

Non-Clinical PERFORMANCE DATA

Non-clinical testing have been conducted to verify that the Hushd Pro Avera meets all design specification which supports the conclusion that it's substantially equivalent (SE) to the predicate device.

A risk analysis on Hushd Pro Avera in accordance with ISO 14971:2007 and FDA guidance document "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea" was conducted. All identified risks have been addressed through device design, biocompatibility and bench testing or through labeling provided to the consumer.

A risk assessment included assessment of the mechanical properties of the material of construction to evaluate its ability to achieve its intended use. The mechanical properties testing of the material of construction were performed by the manufacturer for :

- Flexural Modulus
- Flexural Strength
- Impact Strength

Biocompatibility testing for the final finished device was conducted in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The final finished device was tested for the following biocompatibility parameters:

- Cytotoxicity
- Irritation
- Sensitization
- System Toxicity
- Pyrogen

The subject device is able to achieve its intended use based on the same materials of construction, similar manufactory process and the identical clinical application to the predicate device. There are no new questions of safety or efficacy raised by the Hushd Pro Avera devices compared to the predicate device.

CLINICAL PERFORMANCE DATA

The clinical performance of the subject device is deemed not necessary . The Hushd Pro Avera device has equivalent indication and method of use to its predicated and reference devices, therefore there was no clinical testing to support this device.

No clinical study was performed in association with this submission.

CONCLUSION

The subject device has very similar technological characteristics (i.e. design, function, principle of operation, materials, biocompatibility and sterilization) to the predicate device . The intended use and indications for use of the subject device are the same as the predicate device.

In conclusion, the device is substantially equivalent based on a comparison of intended use, and technological characteristics, the device is safe and effective for its intended use.