October 24, 2025

Good Sleep Co Pte Ltd.
% Joseph Azary
Regulatory Consultant
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K251784
Trade/Device Name: Hushd Pro Z-Link
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: October 15, 2025
Received: October 15, 2025

Dear Joseph Azary:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251784

Device Name
Hushd Pro Z-Link

Indications for Use *(Describe)*
The Hushd Pro Z-Link 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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K251784

510(k) Summary

HUSHD PRO Z-LINK INTRAORAL APPLIANCE FOR SNORING AND SLEEP APNEA

1. SUBMITTER/510(K) HOLDER

Good Sleep Co Pte Ltd.
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Singapore, 069534

Contact Name: Joseph Azary (Aztech Regulatory and Quality LLC.)
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Prepared by: Joseph Azary / Gayathri Manoj

Date Prepared: 10/22/2025

2. DEVICE NAME

Proprietary Name:	Hushd Pro Z-Link
Common/Usual Name:	Intraoral device for snoring and mild to moderate obstructive sleep apnea
Classification Name:	Device Anti-Snoring
Classification Regulation:	21 CFR 872.5570
Classification Product code:	LRK
Classification:	Class 2
Medical Specialty (Panel):	Dental

3. PREDICATE DEVICES

- Predicate Device – Hushd Pro Avera (K232025)
- Reference Device – The Panthera Anti-Snoring Device (K143244)

4. DEVICE DESCRIPTION

The Hushd Pro Z-Link device series are removable intraoral patient-specific device intended for the treatment of snoring and mild to moderate obstructive sleep apnea. The device consists of custom-made maxillary and mandibular splints that fit over the upper and lower teeth, and are connected via a pair of detachable rigid connectors. When linked, the splints function as a mandibular repositioner by holding the lower jaw in a forward position during sleep, thereby preventing the tongue and soft tissues from collapsing into the airway.

Each device consists of one maxillary and one mandibular splint, designed and manufactured using 3D printing technology. The splints incorporate a pair of integrated studs that are located around the canine area for the maxillary splint and around the first molar area for the mandibular splint. These studs interface with slots on the detachable connectors to securely link the two

splints together. This configuration permits the mandible to advance from the baseline position, offering improved patient comfort.

Titration is achieved by replacing the connectors with another pair of a different size. The connectors are available in 1.0 mm incremental lengths, allowing progressive mandibular advancement according to patient tolerance and clinical need. A standard set includes six pairs of connectors, ranging from -1 mm to +5 mm protrusion, while an extended set ranging from +6 mm to +10 mm is available upon request, providing a maximum mandibular protrusion of 10 mm.

The connectors are not elastic and do not contain adjustment mechanisms such as pistons, screws, straps, or repositioning elastics. The rigid connectors are manufactured with medical grade nylon PA12 using commercial injection molding process and are marked for easy identification.

The splints of this device are manufactured using selective laser sintering (SLS) 3D printing with EOS PA2200 polyamide (nylon) PA12 material. This material offers excellent mechanical properties, long-term stability, and has a history of safe use in oral medical devices. The manufacturing process includes mechanical or chemical polishing, cleaning, and rigorous quality control prior to packaging.

The Hushd Pro Z-Link is available for prescription only and designed based on optical or physical impressions taken by a licensed healthcare provider. The splints and connectors are designed exclusively by the device manufacturer and its authorized partners to ensure consistent quality and performance.

Variants/Configurations

There are no variants for this device and it is available only in one configuration.

5. INTENDED USE

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

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject device has the same intended use, materials and operating principles as the predicate devices. Additionally, the differences in technological characteristics do not raise new questions of safety or effectiveness. Therefore, based on the substantial equivalence evaluation represented below, the company concludes that the subject device is equivalent to the predicate devices.

	Hushd Pro Z-Link	**Predicate Device: Hushd Pro Avera (K232025)**	**Reference Device: Panthera Anti-Snoring device (K143244)**	**Comments**
Regulation	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	Same
Class	Class II	Class II	Class II	Same
Product Code	LRK	LRK	LRK	Same
Indications	Reduce or	Reduce or alleviate	Reduce or	Same

for Use	alleviate snoring and mild to moderate obstructive sleep apnea (OSA)	snoring and mild to moderate obstructive sleep apnea (OSA)	alleviate snoring and mild to moderate obstructive sleep apnea (OSA)	
Usage Frequency	Removable intraoral device for single patient multiple use, can be used as Rx only	Removable intraoral device for single patient multiple use, can be used as Rx only	Removable intraoral device for single patient multiple use, can be used as Rx only	Same
Target Population	Adults	Adults	Adults	Same
Mechanism of Action	The device repositions the lower jaw by holding mandible forward during sleep, preventing the tongue and soft tissues of the throat from collapsing into the airway. The separate maxillary and mandibular splints are custom designed for each patient and are linked by a pair of connectors. The splints are integrated with twin-mated studs positioned around the canines (maxillary) and first molars (mandibular). When interfaced via the connectors, the assembly functions as a mandibular repositioner holding the mandible forward	The device repositions the lower jaw by holding mandible forward during sleep, preventing the tongue and soft tissues of the throat from collapsing into the airway. The separate maxillary and mandible splints are designed with twin-mated posts, when interfaced together, function as a mandible repositioner holding the mandible forward during sleep.	The device repositions the lower jaw by holding mandible forward during sleep, preventing the tongue and soft tissues of the throat from collapsing into the airway. The device incorporates connectors and rod system as part of its titration system. These elements are designed to adjust the mandibular advancement, allowing for precise customization of the device to the patient's needs.	All the devices function as Mandibular Repositioners. The subject device uses twin-mated studs and pair of connectors, while the predicate device uses dorsal fins in each splint to keep the lower jaw forward. The use of connectors in the reference device to keep the mandible forward is similar to the subject device.

	during sleep.			
Mandibular advancement range	Upto 10mm at 1mm increments	Upto 10mm at 1mm increments	Significant titration ranges from 16 to 34mm.	Same for both subject and predicate device. While the reference device offers a significant titration range of 16–34 mm.
Fit	Custom fit	Custom fit	Custom fit	Same
Manufacturing process	Made using 3D Printing Technology particularly Selective Laser Sintering	Made using 3D Printing Technology particularly Selective Laser Sintering	Made using 3D Printing Technology particularly Selective Laser Sintering	Same
Cleaning and Maintenance	After each use daily, use a non-abrasive toothpaste to gently clean the device. Periodically, soak the device in a mild denture cleaner or a mixture of water and soap for a more thorough cleanse. Do not use hot water, as it may warp the appliance. Store dry in the case provided.	After each use, use a non-abrasive toothpaste to gently clean the device. Periodically, soak the device in a mild denture cleaner or a mixture of water and soap for a more thorough cleanse.	After each use daily, use a non-abrasive toothpaste to gently clean the device. Periodically, soak the device in a mild denture cleaner or a mixture of water and soap for a more thorough cleanse. Do not use hot water, as it may warp the appliance. Store dry in the case provided.	Same
Material composition	Made up of PA12	Made up of PA12	Made up of PA12	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same

7. PERFORMANCE TESTING AND BIOCOMPATIBILITY

The following standards were either used as a reference and/or for testing of the subject device:

- Charpy Unnotched Impact Strength Testing as per ISO 179-1: 2023
- Flexural Testing as per ISO 178: 2019 Method A
- Shear Testing as per In-house method
- Cytotoxicity Testing per ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity.

- Sensitization Testing per ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.
- Systemic Toxicity Testing per ISO 10993-11 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.
- Irritation Testing per ISO 10993-23 Biological Evaluation of Medical Devices – Part 23: Test for irritation
- Pyrogen Testing per USP 40, National Formulary 35, General Chapter <151> (2017).

8. CONCLUSION

Information presented supports substantial equivalence of the Hushd Pro Z-Link Intraoral Appliance for Snoring and Sleep Apnea to the predicate devices based on similarities in indications for use, manufacturing process, mandibular advancement range and even material used.