



November 25, 2025

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

Re: K252161

Trade/Device Name: Hushd 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: October 28, 2025

Received: October 28, 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
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252161

?

Please provide the device trade name(s).

?

Hushd Avera

Please provide your Indications for Use below.

?

The Hushd Avera device is intended to reduce or alleviate snoring.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) Summary

HUSHD PRO AVERA INTRAORAL APPLIANCE FOR SNORING

1. SUBMITTER/510(K) HOLDER

Good Sleep Co Pte Ltd.
105 Cecil Street,
#18-18, The Octagon
Singapore, 069534

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

Date Prepared: October 28, 2025

2. DEVICE NAME

Proprietary Name:	Hushd Avera
Common/Usual Name:	Intraoral device for snoring
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

- Primary Predicate Device – SnoreRx (K170285)
- Reference Device – Dr. Greenburg’s Hybrid (K111680)

4. DEVICE DESCRIPTION

The Hushd Avera device is a removable intraoral non-patient specific device used for treating snoring. The device consists of multiple trays that fit over the upper and lower teeth. When the upper and lower tray engages, the device functions as a mandibular repositioner holding the mandible forward during sleep thus preventing the tongue and soft tissues of the throat from collapsing into the airway.

The Hushd Avera device is a “Boil and Bite” device where both the upper and lower trays are constructed out of moldable soft ethylene vinyl acetate (EVA) material with rigid polypropylene (PP) outer shells.

Hushd Avera consists of one upper and two lower trays. Each upper tray contains a trapezoidal block on each side of the posterior to mate with the lower tray. An identification mark is placed on the blocks. The blocks and the outer shell of the upper tray are molded in one piece.

SUBSTANTIAL EQUIVALENCE COMPARISON

Each lower tray contains a vertical dorsal fin on each side of the posterior to serve as mating mechanism. The fins are triangular shaped at approximately 12.0mm(H) x 12.0mm(W) x 2.5mm(D). The mating surface of the fins are flat to ensure stable positioning of the upper and lower trays against each other. An identification mark is placed on the dorsal fins. The dorsal fins and the outer shell of the lower tray are molded in one piece.

There are no additional clip-on mechanisms connecting the upper and lower trays.

Relative to the upper tray (U), the first lower tray (L1) is positioned 1.0mm forward from an edge-to-edge position, while the upper tray (U) and the second lower tray (L2) have an additional 2.0mm protrusion. The user can select between the two positions as needed.

Therefore, the maximum protrusion is +3mm from edge to edge while using L2.

Variants/Configurations

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

5. INTENDED USE

The Hushd Avera device is intended to reduce or alleviate snoring 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.

SUBSTANTIAL EQUIVALENCE COMPARISON

	Hushd Pro Avera	Reference Device: SnoreRx (K170285) PRIMARY PREDICATE	Predicate Device: Dr. Greenburg's Hybrid (K111680) REFERENCE PREDICATE	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 for Use	Reduce or alleviate snoring	Reduce or alleviate snoring	Reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA)	Same for both subject and primary predicate device. While reference device is also intended for mild to moderate obstructive sleep apnea (OSA).
Usage frequency	Removable intraoral device for single patient multiple use, can be used as OTC	Removable intraoral device for single patient multiple use, can be used as OTC	Removable intraoral device for single patient multiple use, can be used as Rx only	The subject device and primary predicate device are for OTC use while the reference predicate device is for prescription use only.
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 mandibular advancement is achieved using a series of custom-fit upper (maxillary) and lower (mandibular) splints, which interlock via dorsal fins to hold the lower jaw forward.	The device repositions the lower jaw by adding an elastic component connected between the posterior sections of the trays which impedes the tongue from falling back into the airway. The tray system is designed to posture the lower jaw into several positions, with the intent to increase the airway passage opening.	The device repositions the lower jaw by adding an elastic component connected between the posterior sections of the trays which impedes the tongue from falling back into the airway. The tray system is designed to posture the lower jaw into several positions, with the intent to increase the airway passage opening.	All the devices function as Mandibular Advancement Devices (MAD). The subject device uses dorsal fins in each splint to keep the lower jaw forward while the predicate device and reference device uses tray system.
Mandibular advancement range	Up to 3mm, not incremental advancement	Up to 6mm	Up to 2mm, not incremental advancement	The subject device provides a 2mm advancement up to 3mm. While the reference predicate device provides a fixed advancement of 2mm and the primary predicate device provides an advancement up to 6mm.

SUBSTANTIAL EQUIVALENCE COMPARISON

Fit	Boil-and-bite fit	Boil-and-bite fit	Boil-and-bite fit	Same
Manufacturing process	Commercial injection molding	Commercial injection molding	Commercial injection molding	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, 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.	Same
Material composition	Thermoplastics (Outer – Polypropylene, Inner - EVA)	Thermoplastics (Polycarbonate resin, EVA copolymer)	Thermoplastics (Outer – Polypropylene, Inner - EVA)	All of the devices are composed of thermoplastics. The subject device, primary predicate and reference predicate are all composed of EVA. The primary predicate has polycarbonate whereas the reference predicate has polypropylene which is the same as the subject device.
Sterility	Non-sterile	Non-sterile	Non-sterile	Same

SUBSTANTIAL EQUIVALENCE COMPARISON

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
- Hardness Testing as per ANSI/ADA specification No. 99-2001 (reaffirmed May 2013) clause 4.2
- Tear Strength Testing as per ANSI/ADA specification No. 99-2001 (reaffirmed May 2013) clause 4.3
- Water Sorption Testing as per ANSI/ADA specification No. 99-2001 (reaffirmed May 2013) clause 4.5
- Water Solubility Testing as per ISO 20795-2: 2013 clause 5.2.13
- Tensile Strength Testing as per ASTM D638-22 Type IV
- 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).

SUBSTANTIAL EQUIVALENCE COMPARISON

Summary of Testing		
Standard	Description of Test	Results
ISO 179-1 (2023)	Plastics – Determination of Charpy impact properties Part 1: Non-instrumented impact test Charpy Unnotched Impact Strength Testing	Virgin Material samples (A&B) demonstrated higher impact resistance compared to Mixed samples (C & D).
ISO 178 (2019) Method A	Plastics — Determination of flexural properties Flexural Testing	Mixed material samples (C & D) exhibited higher flexural strength and flexural modulus compared to Virgin samples (A & B).
In-house method	Shear Testing	Samples successfully withstood the applied forces respectively, achieving displacements without premature failure.
ANSI/ADA specification No. 99-2001 (reaffirmed May 2013) clause 4.2	Athletic Mouth Protectors and Materials Hardness Testing	Polypropylene showed higher Shore A hardness, while EVA components provided softer inner surfaces for patient comfort.
ANSI/ADA specification No. 99-2001 (reaffirmed May 2013) clause 4.3	Athletic Mouth Protectors and Materials Tear Strength Testing	Polypropylene demonstrated approximately 4x greater tear resistance than EVA, enhancing long-term durability.
ANSI/ADA specification No. 99-2001 (reaffirmed May 2013) clause 4.5	Athletic Mouth Protectors and Materials Water Sorption Testing	Both materials exhibited low water absorption, with polypropylene showing negligible sorption.
ISO 20795-2: 2013 clause 5.2.13	Dentistry — Base polymers Part 2: Orthodontic base polymers Water Solubility Testing	Solubility values for both polypropylene and EVA were well below the allowable limit.
ASTM D638-22 Type IV	Standard Test Method for Tensile Properties of Plastics Tensile Strength Testing	Polypropylene samples demonstrated significantly higher tensile strength than EVA.
ISO 10993-5 (2009) Cytotoxicity	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity MEM Elution	Non-cytotoxic

SUBSTANTIAL EQUIVALENCE COMPARISON

ISO 10993-10 (2010) Sensitization	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization Guinea Pig Maximization	Non-sensitizer
ISO 10993-11 (2017) Systemic Toxicity	Biological Evaluation of Medical Devices – Part 11: Test for systemic toxicity 0.9% Sodium chloride injection and Sesame oil extract	Non-toxic
ISO 10993-23 (2021) Irritation	Biological Evaluation of Medical Devices – Part 23: Test for irritation Mucosal Irritation Test	Non-irritant
USP 40, National Formulary 35, General Chapter <151> (2017)	Pyrogen Test 0.9% Sodium chloride injection extract	Absence of Pyrogens

8. SAFETY AND EFFICACY

Biocompatibility: A biocompatibility assessment of the device was performed. The purpose of the biocompatibility assessment was to ensure that biocompatibility had been established for the device. The device is biocompatible, based on the identical use of materials of construction of the predicate devices.

Clinical Testing: Human clinical studies were not deemed necessary to evaluate the safety or effectiveness of the subject device. The subject device uses similar manufacturing process as the predicate devices, uses identical materials and has same indications for use.

Risks: As with the predicate devices, the subject device can have risks for dental or soft tissue soreness, TMJ dysfunction, obstruction to oral breathing, dental movement or changes in dental occlusion. The potential hazards, including allergy/irritation, poor fit, and incorrect mandibular protrusion have been systematically evaluated as per ISO 14971: 2019. The Instructions for Use include warnings, precautions and contraindications to address such risks. The device is manufactured using the same equipment and same materials as the predicate devices.

9. CONCLUSION

Information presented supports substantial equivalence of the Hushd Avera Intraoral Appliance for Snoring to the predicate devices based on similarities in intended use, design, principles of operation, material composition and performance specifications. The conclusions drawn from the nonclinical tests and device comparative analysis demonstrate that the Hushd Avera Intraoral Appliance for Snoring device is as safe, as effective, and performs as well as the identified legally marketed predicate device.