



May 19, 2025

Splintek Inc.
Thomas Brown
CEO
15555 W. 108th St.
Lenexa, Kansas 66219

Re: K250122

Trade/Device Name: SleepRight Snore Aid

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: April 15, 2024

Received: April 15, 2025

Dear Thomas Brown:

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

510(k) Number (if known)
K250122

Device Name
SleepRight Snore Aid

Indications for Use (Describe)

Prescription (Rx):

The SleepRight Snore Aid is intended for use on adults 18 years of age or older as an aid for the reduction in mild to moderate obstructive sleep apnea (OSA) and/or snoring.

OTC:

The SleepRight Snore Aid is intended for use on adults 18 years of age or older as an aid for the reduction of snoring.

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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K250122

510(k) Summary

Submitter: Splintek, Inc.
15555 West 108th Street
Lenexa, KS 66219
Ph: 816-531-2008

Company Contact: Thomas W. Brown
Chief Executive Officer (CEO)
Splintek, Inc.

Submission Contact: Thomas W. Brown
Chief Executive Officer (CEO)
Splintek, Inc.

Date Prepared: January 14, 2024

Trade Name: SleepRight® Snore Aid®

Common Name: Intraoral Device for Snoring and/or Obstructive Sleep Apnea

Classification Name: Device, Anti-Snoring

Device Class: Class II

Product Code: LRK, Anti-Snoring Device

CFR Regulation: 21 CFR 872.5570

Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Class II Special Controls Guidance Document for Industry and FDA

Review Panel: Dental

Predicate Devices: SnoreRx (K170825) (Over The Counter)
Apnea Rx Pro (K223901) (Prescription)

Reference Device: SmartGuard Anti-Snore Device (K200657) (Over The Counter)
SleepRight ProRx (K172223) (Biocompatibility Only)

Device Description:

The SleepRight Snore Aid is a customizable adjustable, in 1mm increments up to 6mm total, intraoral mandibular advancement device (MAD). An adjustable stop moves the lower tray, which moves the mandible, to the desired user setting of a position that increases (opens) the pharyngeal space (airway), which aids in minimizing air obstruction and aids in the reduction of snoring during sleep.

The SleepRight Snore Aid consists of two independent, customizable moldable, via hot (not boiling) water and bite method, removable, thermoplastic resin injection molded trays, fitted into the user's mouth, that fit separately over the upper (maxillary) and lower (mandibular) dental arches. The upper tray is provided with an adjustable advancement stop mechanism, one on each side of the rear of the upper tray, that provides the incremental 1mm up to 6mm total adjustment. The lower tray is provided with a fin, one on each side of the tray. As the adjustable advancement stop mechanism on each side of the upper tray is incrementally adjusted, the adjustable advancement stop mechanism on each side of the upper tray engages the fin, in a mating position on each side of the lower tray, stabilizing the mandible in a neutral posture or advances the mandible forward until the desired position that opens the airway and aids in a reduction of snoring during sleep is obtained by the user. Because the mandible is attached to the Oropharynx airway tissues (throat), and its posterior movement collapses the airway, stabilizing the mandible in a neutral or advanced forward position opens the airway for improved breathing. Having two independent dental arch trays allows for freedom of movement of the jaw musculature resulting in more user comfort, compliance and efficacy. Necessary Inspiratory and expiratory rapid expulsion of air is also improved.

Indications for Use for Over the Counter (OTC):

The SleepRight Snore Aid is intended for use on adults 18 years of age or older as an aid for the reduction of snoring.

Indications for Use for Prescription (Rx):

The SleepRight Snore Aid is intended for use on adults 18 years of age or older as an aid for the reduction in mild to moderate obstructive sleep apnea (OSA) and/or snoring.

Comparison Of Technological Characteristics:

There are no technological differences between the Over the Counter (OTC) and Prescription (Rx) versions of the SleepRight Snore Aid. The SleepRight Snore Aid can be fitted by and adjustments made by the user or a clinician.

The SleepRight Snore Aid uses the same or similar technological characteristics as the predicate and reference devices. The SleepRight Snore Aid and the predicate and reference devices provide incrementally adjustable means to move the lower tray and move the mandible to the desired user setting of a position that increases (opens) the pharyngeal space (airway), aiding in minimizing air obstruction and aiding in a reduction of snoring during sleep.

All devices are substantially equivalent in design, materials, manufacturing, intended use, labeling, function, safety and efficacy.

Refer to the Technological Comparison Chart for the SleepRight Snore Aid, (Proposed Device), and the predicate and reference devices.

Technological Characteristics Comparison Chart for SleepRight Snore Aid, Predicate and Reference Devices

Devices	Proposed Device	Predicate Device	Predicate Device	Reference Device	Differences
Trade Name	SleepRight Snore Aid	SnoreRx	Apnea Rx Pro	SmartGuard Anti-Snore Device	N/A
510(k)	N/A	K170825	K223901	K200657	N/A
Class	II	II	II	II	None
Code	LRK	LRK	LRK	LRK	None
CFR Regulation	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	None
Classification Name	Intraoral Anti-Snoring Device	Intraoral Anti-Snoring Device	Intraoral Anti-Snoring Device	Intraoral Anti-Snoring Device	None
Indications For Use (OTC/Rx)	OTC/Rx	OTC	Rx	OTC	OTC/Rx
Intended Use OTC	Intended for use on adults 18 years of age or older as an aid for the reduction of snoring	Intended for use on adults 18 years of age or older as an aid for the reduction of snoring	N/A	Intended for use on adults 18 years of age or older as an aid for the reduction of snoring	None
Intended Use Rx	Intended for use on adults 18 years of age or older as an aid for the reduction in mild to moderate obstructive sleep apnea (OSA) and/or snoring	N/A	Intended for use on adults 18 years of age or older as an aid for the reduction in mild to moderate obstructive sleep apnea (OSA) and/or snoring	N/A	None
Labeling Instructions Contraindications Warnings Precautions	Per Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Class II Special Controls Guidance Document for Industry and FDA	Per Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Class II Special Controls Guidance Document for Industry and FDA	Per Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Class II Special Controls Guidance Document for Industry and FDA	Per Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Class II Special Controls Guidance Document for Industry and FDA	None

Device Design And Function	Mandibular Advancement Device (MAD) providing incrementally adjustable advancement to the mandible which increases (opens) pharyngeal space (airway) to aid in the reduction of snoring	Mandibular Advancement Device (MAD) providing incrementally adjustable advancement to the mandible which increases (opens) pharyngeal space (airway) to aid in the reduction of snoring	Mandibular Advancement Device (MAD) providing incrementally adjustable advancement to the mandible which increases (opens) pharyngeal space (airway) to aid in the reduction of snoring	Mandibular Advancement Device (MAD) providing incrementally adjustable advancement to the mandible which increases (opens) pharyngeal space (airway) to aid in the reduction of snoring	None
Device Manufacturing	Injection molded	Injection molded	Injection molded	Injection molded	None
Device Operational Adjustment	Adjust stop mechanism on each side of upper tray in 1mm increments moving the bottom tray until desired setting	Hold device and squeeze both sides of upper tray while moving both sides of the bottom tray in 1mm increments until desired setting	Hold device and squeeze both sides of upper tray while moving both sides of the bottom tray in 1mm increments until desired setting	Incrementally sized bars 1mm to 6mm placed on each side of upper and lower trays moving the bottom tray until desired setting	All devices move both sides of the bottom tray incrementally in 1mm increments to desired setting
Device Fitting Thermal Setting Resins	Molded (fitted) to upper and lower dental arches of individual user's teeth via warm water and bite method	Molded (fitted) to upper and lower dental arches of individual user's teeth via boil and bite method	Molded (fitted) to upper and lower dental arches of individual user's teeth via boil and bite method	Molded (fitted) to upper and lower dental arches of individual user's teeth via boil and bite method	SleepRight Snore Aid requires 150°F water vs 212°F boiling water for molding (fitting)
Device Use	Home Single user Reusable	Home Single user Reusable	Home Single user Reusable	Home Single user Reusable	None
Device Cleaning	Clean with toothbrush and toothpaste rinse with water after each use	Clean with toothbrush and toothpaste rinse with water after each use	Clean with toothbrush and toothpaste rinse with water after each use	Clean with toothbrush and toothpaste rinse with water after each use	None

Device Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	None
Device Materials	Polycarbonate Ethylene Vinyl Acetate Polypropylene Polycaprolactone	Polycarbonate Ethylene Vinyl Acetate	Polycarbonate Ethylene Vinyl Acetate	Polycarbonate Ethylene Vinyl Acetate	Polypropylene Polycaprolactone All materials used from prior FDA cleared devices.
Biocompatibility Testing Of Materials	ISO 10993 Cytotoxicity Sensitization Irritation	ISO 10993 Cytotoxicity Sensitization Irritation	ISO 10993 Cytotoxicity Sensitization Irritation	ISO 10993 Cytotoxicity Sensitization Irritation	None

Risks To Health:

Per the Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Class II Special Controls Guidance Document for Industry and FDA, Section 5, the FDA has identified risks to health generally associated with the use of intraoral devices for snoring and/or obstructive sleep apnea. The FDA has provided recommended mitigation measures for these identified risks.

Identified risks:

- Intraoral gingival, palatal or dental soreness
- Temporomandibular Joint (TMJ) Dysfunction Syndrome
- Obstruction of oral breathing
- Loosening or flaring of lower anterior teeth or general tooth movement

Recommended mitigation measures:

- Material Composition
- Testing
- Labeling

Testing - Biocompatibility:

Biocompatibility Testing, of materials that comprise the SleepRight Snore Aid, has been previously conducted on the same materials for the Splintek, Inc. SleepRight Pro Rx Dental Guard and predicate devices. Use of Fourier Transform Infrared Spectroscopy was used to identify the identity of the Polycarbonate material of the predicate and reference devices.

The Biocompatibility Testing of the same materials included:

ISO 10993-5 Cytotoxicity

ISO 10993-10 Sensitization

ISO 10993-23 Irritation

Results concluded Biocompatibility Testing of materials to be in accordance with ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization) and ISO 10993-23 (Irritation).

In accordance with FDA's classification, the SleepRight Snore Aid is considered to have permanent contact with mucosal membranes. As such, the relevant endpoints include cytotoxicity, sensitization, irritation, subacute/subchronic toxicity, and genotoxicity. Based on the material equivalence to predicate devices and previous testing in legally marketed devices, subacute/subchronic toxicity and genotoxicity were not tested and are justified as not needed per ISO 10993-1.

All biocompatibility tests performed passed the acceptance criteria in accordance with applicable ISO standards.

As the materials and processes for the Splintek, Inc. SleepRight Snore Aid are identical to the FDA 510(k) Splintek, Inc. SleepRight Pro Rx Dental Guard, SleepRight Advance dental guard and predicate and reference devices, Biocompatibility Testing of materials was not conducted.

Testing - Clinical:

Clinical testing was not conducted as the SleepRight Snore Aid is substantially equivalent to the predicate and reference devices in relation to design, materials, manufacturing, intended use, labeling and function.

Testing - Non-Clinical:

Physical property data for polycarbonate mechanical properties include:

- Flexural Strength
- Elastic Modulus
- Compressive Strength
- Surface Hardness
- Water Sorption
- Water Solubility

These properties are representative of the final finished component as the material is used unmodified and processed per the manufacturer specifications.

The SleepRight Snore Aid device materials have been tested to various properties such as Tensile Properties and Flexural Properties by each material manufacturer as noted in Technical Data Sheets. The materials that comprise the SleepRight Snore Aid are the same materials that comprise the FDA Cleared 510(k) SleepRight Pro Rx, SleepRight Advance Dental Mouthguard, predicate and reference devices.

The physical properties of each component material were assessed using manufacturer-supplied technical data sheets. Testing included ASTM D790 (Flexural Strength), ASTM D638 (Tensile Strength), ASTM D695 (Compressive Strength), ASTM D2240 (Surface Hardness), ASTM D570 (Water Sorption), and ASTM D896 (Water Solubility). These tests were conducted by the material manufacturers and documented in each material's Technical Data Sheet (TDS). All materials met or exceeded benchmark acceptance criteria for intraoral use in accordance with the applicable ASTM standards.

Device Comparison Conclusion:

The SleepRight Snore Aid has the same or similar technological characteristics as the predicate and reference devices. The SleepRight Snore Aid, and the predicate devices, are intraoral, fit full upper and lower arches, incrementally adjustable by 1mm, anti-snoring, jaw repositioning, mandibular advancement devices with the same indicated and intended use.

All devices are intended for repeated, long-term mucosal membrane contact and share the same tissue contact classification and duration of exposure.

The SleepRight Snore Aid, and the predicate and reference devices, are substantially equivalent in design, materials, manufacturing, intended use, labeling, function, safety and efficacy.

In comparison, the SleepRight Snore Aid is substantially equivalent to the predicate and reference devices.