November 3, 2025

Nightguard Express, LLC
Flavia Alonso
Quality Manager
571 W. Main Street
Lewisville, Texas 75057

Re: K252698
Trade/Device Name: NightGuard Aire Max
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, LQZ
Dated: October 31, 2025
Received: October 31, 2025

Dear Flavia Alonso:

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
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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)*
K252698

Device Name
NightGuard Aire Max

Indications for Use *(Describe)*
The NightGuard Aire Max is a removable medical device that is fitted in the patient's mouth and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Summary Prepared:	08/25/2025
Submission Sponsor:	Nightguard Express, LLC 571 W. Main St, Suite 220 Lewisville, TX 75057 214-222-0507 flavia@nightguard.express
Submission Correspondent:	Flavia Alonso Quality Manager 469-258-0494 flavia.alonso@sentientreality.com
Proprietary Name:	NightGuard Aire Max
Common Name:	Intraoral Devices for Snoring and/ or Obstructive Sleep Apnea
Classification Name:	Intraoral Devices for Snoring and/ or Obstructive Sleep Apnea
Regulation Number:	21 CFR 872.5570
Regulation Name:	Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Device Class:	Class II
Classification Panel:	Dental
Product Code:	LRK, LQZ
Predicate Device:	K232735 - EMA 3D

Indication for Use Statement: The NightGuard Aire Max is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Intended Use: The NightGuard Aire Max is an intraoral appliance intended for the treatment of mild to moderate Obstructive Sleep Apnea (OSA) and habitual snoring.

Device Description: The NightGuard Aire Max is a custom made intraoral appliance intended to treat mild to moderate Obstructive Sleep Apnea (OSA) and habitual snoring. The device's primary function is mandibular advancement, which repositions the lower jaw forward during sleep. This forward positioning helps reduce airway obstruction, promoting improved airflow and alleviating symptoms associated with snoring and Obstructive Sleep Apnea (OSA). The device comprises two custom made trays, each featuring two embedded button hooks on each side, and a pair of elastic bands. The hooks are positioned at a distance of 20mm apart from the upper tray hook to the bottom tray hook. These hooks serve as secure attachment points for the elastic bands, which serve to keep the trays in place. The bands are available in four different sizes (20mm, 19mm, 18mm, and 17mm) ensuring a functional, customizable fit for each patient. The upper and lower trays each support a structural element, and the structural elements together maintain an open airway. In particular, the lower tray features an anterior platform with a bump elevation located at a position corresponding to a patient's central incisors. This bump serves as a specific point of contact to maintain an open airflow space, supporting the functionality of the anterior platform. The upper tray includes a flat plane at a position corresponding to the patient's central incisors, which

works in conjunction with the bump elevation on the lower tray to facilitate airflow during use. The upper and lower trays are manufactured using one of three FDA-cleared, biocompatible materials: Dental LT Comfort Resin, KeySplint Hard Resin, or KeySplint Soft Resin, each of which is suitable for long-term contact with oral tissues.

Substantial Equivalence Discussion:

Table 15-1: Comparison Summary of Technological Characteristics

Technological Characteristics	NightGuard Aire Max	EMA 3D (Predicate)
Intended Use		
Intraoral device	✔	✔
Helps reduce habitual snoring	✔	✔
Treatment of mild to moderate sleep apnea	✔	✔
Night time only use	✔	✔
Used at home and/or clinical settings	✔	✔
Used by adults	✔	✔
Prescription only	✔	✔
Design		
Custom made	✔	✔
Removable device	✔	✔
Separated upper and lower pieces	✔	✔
Works by mandibular advancement. Hook system with Elastic Bands	✔	✔
Can be adjusted by patient or dentist	✔	✔
Permits patient to breathe through mouth	✔	✔
Material		
Trays made of FDA-Cleared Resin	✔	✔

The following table provides a comprehensive comparison of the NightGuard Aire Max and the predicate device. The NightGuard Aire Max maintains the same essential performance and safety characteristics as the predicate device, confirming its substantial equivalence.

Table 15-2: Comparison of Characteristics

SPECIFICATION	NightGuard Aire Max	EMA 3D (Predicate)	COMPARISON
Picture			N/A
510 (k) Number	N/A	K232735	N/A
Manufacturer	Nightguard Express, LLC	EMA Sleep Incorporated	N/A
Regulatory Classification	21 CFR 872.5570	21 CFR 872.5570	Same
Classification	II	II	Same
Product Code	LRK	LRK	Same
Intended Use	The NightGuard Aire Max is an intraoral appliance intended for the treatment of mild to moderate Obstructive Sleep Apnea (OSA) and habitual snoring.	The EMA 3D device is an intra-oral device used for treating snoring and mild to moderate Obstructive Sleep Apnea (OSA).	Same
Environment of	Home and clinical settings.	Home and clinical settings.	Same

Use			
Availability (OTC or Rx)	Rx	Rx	Same
Indications for Use	The NightGuard Aire Max is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The EMA 3D is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Same
Method of Use	Removable and reusable intraoral mandibular repositioning device for a single patient.	Removable and reusable intraoral mandibular repositioning device for a single patient.	Same
Target Population	Adults, 18 years or older, diagnosed with mild to moderate sleep apnea	Adults, 18 years or older, diagnosed with mild to moderate sleep apnea	Same
Operation Mechanism	The device consists of an upper and lower tray that work in conjunction with each other via an embedded button hook and variable size elastic bands that allows the dental professional to properly adjust the devices to patient dentition and physiological need ultimately reducing pharyngeal obstruction through mandibular advancement.	The device consists of an upper and lower tray that work in conjunction with each other via an embedded button hook and variable size elastic bands that allows the dental professional to properly adjust the devices to patient dentition and physiological need ultimately reducing pharyngeal obstruction through mandibular advancement.	Same
Functionality	The device functions as a mandibular repositioner, which acts to increase the patient's pharyngeal space by reducing obstructions of the airway during sleep and improves the patient's ability to exchange air during sleep.	The devices function as mandibular repositioners, which act to increase the patient's pharyngeal space by reducing obstructions of the airway during sleep and improve their ability to exchange air during sleep.	Same

Design	The device consists of two custom-fitted trays that fit over the upper and lower dentition. Each tray is designed to securely encase the teeth. There are four button hooks on the NightGuard Aire Max device (two hooks per tray, two trays top and bottom). The hooks are placed at a distance of 20mm apart from the top tray hook to the bottom tray hook. The upper tray features a flat plane on the central incisors, while the lower tray has a platform with a bump in the same area. This bump serves as a single point of contact with the flat plane on the upper tray, helping to maintain an open airflow space.	The device consists of two custom-fitted trays that fit over the upper and lower dentition. Each tray is designed to securely encase the teeth. There are four button hooks utilized on the EMA 3D device (two hooks per tray, two trays top and bottom). The hooks are placed at a distance of 21mm apart from the top tray hook to the bottom tray hook, measured center to center. The lower tray features two separate bite pads at the back, each serving as a structural point of contact.	Similar – NightGuard Aire Max has one point of contact in the front, while the EMA 3D has two bite pads in the back of the lower tray. Hook spacing differs by 1mm.
Means of Advancing the Mandible	Lower jaw advancement adjusted by elastic bands of varying sizes.	Lower jaw advancement, adjusted by elastic bands of varying sizes and strengths.	Same
Adjustment	Can be adjusted by the patient or dentist.	Can be adjusted by the patient or dentist.	Same
Tray Material Upper and Lower Arch	KeySplint Hard/ KeySplint Soft / or Dental LT Comfort	KeySplint Hard/ KeySplint Soft	Same – plus 2 additionals
Fabrication	3D Printed	3D Printed	Same
Material Connecting Mechanism	Thermoplastic Vulcanizate (TPV) No colorant utilized for Elastic Bands. TPV is a type of TPE.	Thermoplastic Elastomer (TPE) and colorant for White, Yellow, and Blue Elastic Straps. No colorant utilized for clear Elastic Straps.	Similar – both use materials from the same thermoplastic elastomer (TPE) family.

Connecting Mechanism	Button hook system with Elastic Straps	Button hook system with Elastic Straps	Same
Range and Precision of Adjustment	+/-1mm	+/-1mm	Same
Maximum Mandibular Advancement	14mm	14mm	Same
Biocompatible	Yes	Yes	Same
Usage	Reusable by the same patient. Night time only	Reusable by the same patient. Night time only	Same
Sterility	Non-Sterile	Non- Sterile	Same

Comparison Discussion: The NightGard Aire Max and EMA 3D are both custom made, removable intraoral appliances intended for the treatment of mild to moderate Obstructive Sleep Apnea (OSA) and habitual snoring. Both devices share the same intended use, technological characteristics, indications of use, and mechanism of action. The predicate device and the proposed device are manufactured using 3D printing technology and offer the same FDA-cleared biocompatible materials, KeySplint Soft and KeySplint Hard resins, choices. The NightGuard Aire Max offers an additional material choice, Dental LT Comfort Resin, providing flexibility in manufacturing.
The designs of both appliances are similar and they share the same concept of maintaining an open airway.

Non-Clinical Performance Data: Risk analysis has been performed to identify potential hazards associated with the NightGuard Aire Max, and appropriate measures have been implemented to ensure patient safety. Biocompatibility data for the resins (Dental LT Comfort, KeySplint Soft, KeySplint Hard) and elastic bands used in the device are provided through technical data sheets from the manufacturers. The resins have been FDA-cleared for long term oral contact and thus have undergone biocompatibility testing, including assessments for cytotoxicity, irritation, and sensitization, in accordance with ISO 10993 standards. As a result, the resins are confirmed to be safe for use in medical devices that come into long term contact with oral tissue. The elastic band material is FDA-food listed and complies with USP Class VI requirements for medical grade plastics. In addition, mechanical testing was performed by Submitter NGEX. This testing included fatigue and wear testing of the appliance and elastic bands and this

testing further demonstrates strong wear resistance and endurance for long term use without compromising performance. Further, a sleep test demonstrated that the device effectively contributes to airway opening and supports its intended purpose of improving airflow during sleep.

Clinical Testing: Human clinical studies were not deemed necessary to evaluate the safety or effectiveness of the NightGuard Aire Max. The device does not introduce a new design concept compared to the predicate device, EMA 3D. Instead, it builds upon a proven design that does not raise new questions of safety or effectiveness. Furthermore, the NightGuard Aire Max shares the same indications for use as the predicate device, targeting mild to moderate Obstructive Sleep Apnea (OSA), and habitual snoring in adults. This substantial equivalence supports the conclusion that additional clinical studies are unnecessary.

Statement of Substantial Equivalence: The NightGuard Aire Max is substantially equivalent to the predicate device, EMA 3D (K232735). Both devices are classified under 21 CFR 872.5570, Class II, with the same product code (LRK), and share the same intended use and technological characteristics. They achieve mandibular advancement through interchangeable elastic bands to maintain an open and unobstructed airway during sleep.