July 31, 2026

DnB Innovations, LLC
Colette Cozean
Regulatory Consultant
1814 Mason Ct.
Keller, Texas 76248

Re: K261912
Trade/Device Name: SnØreNegatØr
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: June 8, 2026
Received: June 8, 2026

Dear Colette Cozean:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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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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)*
K261912

Device Name
SnØreNegatØr

Indications for Use *(Describe)*
OTC: The SnØreNegatØr is intended to treat snoring in adults at least 18 years old.
Rx: The SnØreNegatØr is intended to treat snoring and mild to moderate obstructive sleep apnea in adults at least 18 years old.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K261912

510(k) Summary

Prepared on: 2026-06-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	DnB Innovations LLC
Applicant Address	1814 MASON COURT KELLER TX 76248 United States
Applicant Contact Telephone	949-855-2885
Applicant Contact	Dr. Colette Cozean
Applicant Contact Email	colettecozean@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SnØreNegatØr
Common Name	Mouthguard
Classification Name	Device, Anti-Snoring
Regulation Number	872.5570
Product Code(s)	LRK, LQZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K252531	Myosa S1, Myosa S2	LRK,LQZ

Device Description Summary

21 CFR 807.92(a)(4)

The SnØreNegatØr is an Over the Counter (OTC) intraoral appliance designed to reduce snoring by increasing upper airway patency during sleep and a Prescription (Rx) intraoral appliance designed to treat snoring and mild to moderate obstructive sleep apnea in adults at least 18 years old. This is achieved through a dual-action mechanism: mandibular advancement and tongue stabilization. The device repositions the lower jaw forward slightly, which helps prevent airway collapse by tightening the surrounding soft tissues and muscles. A flexible tongue pad gently supports the tongue to prevent posterior displacement, reducing airway obstruction caused by tongue relaxation. The mouthguard device requires no pre-use fitting, as the flexible nature of the material conforms to various dental alignments and anatomical detail. It also provides two through holes, one on each side of the mouth, for breathing.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

OTC: The SnØreNegatØr is intended to treat snoring in adults at least 18 years old.
Rx: The SnØreNegatØr is intended to treat snoring and mild to moderate obstructive sleep apnea in adults at least 18 years old.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device, SnØreNegatØr, has the same intended use as the predicate devices and product codes LRK and LQZ.

Technological Comparison

21 CFR 807.92(a)(6)

SnØreNegatØr uses the same material as the predicate device – a medical grade silicone. The subject and predicate devices all have slight mandibular advancement and have tongue positioning. All products have similar labeling including in the OTC labeling a warning

for sleep apnea and an available test method (Stop Bang).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

No performance testing was required to determine substantial equivalence.