



June 11, 2026

Endeavor Commerce, LLC
% Purity Chen
Manager
Shanghai Spica Management Consulting Co., Ltd.
609 Rm., #133 Shengang Ave., Pudong New District
Shanghai, 201306
China

Re: K261251

Trade/Device Name: Snorbliss® Anti-Snoring Device

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, 2026

Received: April 16, 2026

Dear Purity Chen:

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,



Bobak
Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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)
K261251

Device Name
Snorbliss® Anti-Snoring Device

Indications for Use (Describe)
Snorbliss® Anti-Snoring Device is intended to aid in 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.

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

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Summary

1.Submitter Information

Manufacturer Name:Endeavor Commerce LLC

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Contact Person:HASEM BASARAN

2.Application correspondent

Company Name:Shanghai Spica Management Consulting Co., Ltd.

Address:609 Room, No.133 Shengang Avenue, Pudong New District, Shanghai, China

Tel:86-17802157742

Email:Purity@spicagloble.com

Contact Person:Purity Chen

3.Date prepared:

March 30, 2026

4.Device identification

Trade Name	Snorbliss® Anti-Snoring Device
Model	Pro 2.0
Regulation Number	21 CFR 872.5570
Regulation Name	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Device Classification	Class II
Product Code	LRK
Panel	Dental

5.Predicate device information

Summary

Sponsor	FISSIONTECH LLC
Trade/Device Name	Difiney Anti Snoring Device
510(K) number	K233850
Regulation Number	21 CFR 872.5570

6.Indications for use

Snorbliss® Anti-Snoring Device is intended to aid in the reduction of snoring.

7.Device description

The product consists of three parts. The first part is the upper brace, the second part is the lower brace, and the third part is the adjustment connecting strap. The materials used are PP and EVA. The upper brace and lower brace are made of PP and EVA respectively, while the connecting strap is made of PP.

8.Performance Testing - Clinical

Not Applicable.

9.Performance Testing - Animal

Not Applicable.

Summary

Technological Characteristic Comparison

Provided below is a comparison of the subject device with the predicate device.

Table 16A: General Comparison

Item	Subject Device	Predicate Device (K233850)	Comparison
Product Code	LRK	LRK	Same
Class	Class II	Class II	Same
Classification Name	Anti-Snoring Device	Anti-Snoring Device	Same
Proprietary Name	Snorbliss® Anti-Snoring Device	Difiney Anti Snoring Device	/
Technological Features	The Snorbliss® Anti - Snoring Device gently moves the lower jaw forward, helping to keep the airway open. This improves airflow, supports easier breathing, and reduces snoring sounds.	Difiney Anti Snoring Device helps reduce snoring by moving the lower jaw forward to open your airway to improve breathing allowing air to flow freely without the unhealthy and annoying sound of snoring.	Similar
Intended Use	Snorbliss® Anti-Snoring Device is intended to aid	The Difiney Anti Snoring device is intended to help reduce snoring in adults 18 years of age or	Similar

Summary

	in the reduction of snoring.	older.	
Materials	- Polypropylene - Ethylene vinyl acetate copolymer	- Polycarbonate resin - Ethylene vinyl acetate copolymer	Similar
Desirable Characteristics	Home use, heat sensitive / moldable, adjustable jaw advancement position	Home use, heat sensitive / moldable, adjustable jaw advancement position	Same
Specifications: - Physical: - Mechanical: - Single use:	- Custom-fitted intraoral device - Repositions mandible anteriorly up to 7 mm - Reusable	- Custom-fitted intraoral device - Repositions mandible anteriorly up to 4 mm - Reusable	Similar
Sterility	Non-sterile	Non-sterile	Same
Biocompatibility	ISO 10993	ISO 10993	Same

Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

Biocompatibility test

Bio-compatibility assessment was conducted in accordance with ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Physical properties

- ASTM D790-17 for flexural strength and flexural modulus.
- ASTM D638-22 for Tensile Strength and Elongation at break.

Summary

- ASTM D570-22 for water absorption.
- ASTM D3418-21 for melting temperature.
- ASTM D792-20 for Density.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Snorbliss® Anti-Snoring Device is substantially equivalent to the legally marketed predicated device K233850.