May 8, 2025

Fissiontech LLC
% Chang Libray
Manager
Shanghai Spica Management Consulting Co., Ltd.
609 Room, No.133 Shengang Avenue, Pudong New District
Shanghai, 200120
CHINA

Re: K250482
Trade/Device Name: Advanced Anti Snoring Device 4.0 Clear/ Advanced Anti Snoring Device 4.0 Blue
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: December 5, 2024
Received: February 19, 2025

Dear Chang Libray:

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250482

Device Name
Advanced Anti Snoring Device 4.0 Clear/ Advanced Anti Snoring Device 4.0 Blue

Indications for Use *(Describe)*
The Advanced Anti Snoring Device 4.0 is intended to help reduce snoring in people 18 years of age or older.

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-K250482

Type of submission	Traditional
Date prepared	May 7, 2025

Submission sponsor

Manufacturer Name	FISSIONTECH LLC
Address	1 LIBERTY STREET,FLOOR 3, NEW YORK CITY NEW YORK 10006
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Device identification

Trade Name	Advanced Anti Snoring Device 4.0 Clear/ Advanced Anti Snoring Device 4.0 Blue
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

Application correspondent

Company Name	Shanghai Spica Management Consulting Co., Ltd.
Address	609 Room, No.133 Shengang Avenue, Pudong New District, Shanghai, China

Tel	86-13020102321
Email	Libray@spicagloble.com
Contact Person	Libray Chang

Predicate device information

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

Indications for use

The Advanced Anti Snoring Device 4.0 is intended to help reduce snoring in people 18 years of age or older.

Device description

The Advanced Anti Snoring Device 4.0 is designed to reduce snoring by gently repositioning the lower jaw forward, which opens the airway and allows for smoother airflow during sleep. By adjusting the position of the lower jaw, the device helps prevent the throat tissues from collapsing and blocking airflow, which is a common cause of snoring.
The 4.0 version is customizable, allowing users to set the lower jaw advancement up to 6mm, providing a personalized fit for maximum comfort and effectiveness. This forward positioning also reduces vibrations in the airway, which are often responsible for the snoring sound.

Performance Testing - Clinical

Not Applicable.

Performance Testing - Animal

Not Applicable.

Technological Characteristic

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

Table 4A: General Comparison

Item	**Subject Device**(K250482)	**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	Advanced Anti Snoring Device 4.0 Clear/ Advanced Anti Snoring Device 4.0 Blue	Difiney Anti Snoring Device	/
Technological Features	Advanced Anti Snoring Device 4.0 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.	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.	Same
Intended Use	The Advanced Anti Snoring Device 4.0 is intended to help reduce snoring in people 18 years of age or older.	The Difiney Anti Snoring device is intended to help reduce snoring in adults 18 years of age or older.	Same
Materials	- Polycarbonate resin	- Polycarbonate resin	Same

	- Ethylene vinyl acetate copolymer	- Ethylene vinyl acetate copolymer	
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 - Reusable	- Custom-fitted intraoral device - Repositions mandible anteriorly - Reusable	Similar
Mandibular advancement range	Repositions mandible anteriorly up to 6 mm at 1mm increment	Repositions mandible anteriorly up to 4 mm at 1mm increment	Different 1
Design	Small anterior protrusion present	No anterior protrusion	Different 2
Manufacturing Process	Injection molding	Injection molding	Same
Sterility	Non-sterile	Non-sterile	Same
Biocompatibility	ISO 10993	ISO 10993	Same

Different 1

The difference between a maximum advancement of 6 mm versus 4 mm is that 6 mm provides a greater degree of airway expansion, which can more effectively reduce snoring. Both devices advance in 1 mm increments, the difference is that the subject device provides 2 mm greater advancement than the predicate device; no other design features have been changed. Therefore, this difference does not impact the safety or effectiveness of the product.

Different 2

The small protrusion on the predicate device may cause discomfort for the user. In the subject device, we have removed this protrusion to improve wearing comfort. This is purely a design difference and does not affect the device's safety or effectiveness.

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
The materials used for the device have passed the following performance tests: flexural strength and flexural modulus, tensile strength and elongation at break, water absorption, melting temperature, and density.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Advanced Anti Snoring Device 4.0 Clear/ Advanced Anti Snoring Device 4.0 Blue is substantially equivalent to the legally marketed predicated device K233850.