



October 29, 2025

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

Re: K253355

Trade/Device Name: Difyney Advanced Anti Snoring Device 4.0

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: September 15, 2025

Received: September 30, 2025

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 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253355

?

Please provide the device trade name(s).

?

Difiney Advanced Anti Snoring Device 4.0

Please provide your Indications for Use below.

?

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

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	FISSIONTECH LLC
Applicant Address	1 LIBERTY STREET, FLOOR 3, NEW YORK CITY NEW YORK 10006 NEW YORK NEW YORK 10006 United States
Applicant Contact Telephone	314 475 4711
Applicant Contact	Mr. Mike Lee
Applicant Contact Email	mike@everymarket.com
Correspondent Name	Shanghai Spica Management Consulting Co., Ltd.
Correspondent Address	609 Room, No.133 Shengang Avenue, Pudong New District, Shanghai, China Shanghai 200120 China
Correspondent Contact Telephone	86-17802157742
Correspondent Contact	Ms. Purity Chen
Correspondent Contact Email	Purity@spicaglobe.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Difiney Advanced Anti Snoring Device 4.0
Common Name	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Classification Name	Device, Anti-Snoring
Regulation Number	872.5570
Product Code(s)	LRK

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K250482	Advanced Anti Snoring Device 4.0 Clear/ Advanced Anti Snoring Device 4.0 Blue	LRK

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Difiney 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.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The device has the same indications for use in comparison to the predicate device(s).

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The new device has the same Specifications in comparison to predicate device. The new device has the same Technological Features, Intended Use, Materials, Desirable Characteristics, Sterility, Biocompatibility in comparison to those of the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The conclusion drawn from the Verification and Validation Summary demonstrates that the subject device Difiney Advanced Anti Snoring Device 4.0 is substantially equivalent to the legally marketed predicate device K250482.