April 18, 2024

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

Re: K233850
Trade/Device Name: Difiney 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 8, 2024
Received: April 8, 2024

Dear Libray Chang:

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.

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

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)*
K233850

Device Name
Difiney Anti Snoring Device

Indications for Use *(Describe)*
The Difiney Anti Snoring Device is intended to help reduce snoring in adults 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.

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510(K) Summary
K233850

Type of submission	Traditional
Date prepared	April 8, 2024

Submission sponsor

Manufacturer Name	FISSIONTECH LLC
Address	1 LIBERTY STREET,FLOOR 3, NEW YORK CITY NEW YORK 10006
Tel	314 475 4711
Email	mike@everymarket.com
Contact Person	Mike Lee

Device identification

Trade Name	Difiney Anti Snoring Device
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

Summary

Contact Person	Libray Chang

Predicate device information

Sponsor	Apnea Sciences Corporation
Trade/Device Name	SnoreRx
510(K) number	K170285
Regulation Number	21 CFR 872.5570

Indications for use

The Difiney Anti Snoring device is intended to help reduce snoring in adults 18 years of age or older.

Device description

The Difiney Anti Snoring device is an intraoral device that is composed of an upper and lower intraoral trays with a handle that is used during the process of customizing the trays. The Difiney Anti Shoring device repositions the jaw anteriorly relative to the maxilla in order to increase the patient's pharyngeal space to improve the ability to exchange air and decrease air turbulence, a causative factor in snoring.

Performance Testing - Clinical

Not Applicable.

Performance Testing - Animal

Not Applicable.

Technological Characteristic Comparison

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

Table 14A: General Comparison

Item	**Subject Device**	**Predicate Device** (K170285)	**Comparison**
Product Code	LRK	LRK	Same
Class	Class II	Class II	Same
Classification Name	Anti-Snoring Device	Anti-Snoring Device	Same
Proprietary Name	Difiney Anti Snoring Device	SnoreRx	/
Technological Features	Mandibular repositioning to advance the mandible relative to the maxilla to increase pharyngeal space.	Mandibular repositioning device that advances the lower jaw to increase pharyngeal space.	Similar
Intended Use	The Difiney Anti Snoring device is intended to help reduce snoring in adults 18 years of age or older.	Minimize air turbulence that causes snoring. Device is intended for OverThe-Counter use.	Similar

Materials	- Polycarbonate resin - Ethylene vinyl acetate copolymer	- Polycarbonate resin - Ethylene vinyl acetate copolymer	Same
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 4 mm - Reusable	- Custom-fitted intraoral device - Repositions mandible anteriorly up to 6 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.
- ASTM D570-22 for water absorption.
- ASTM D3418-21 for melting temperature.
- ASTM D792-20 for Density.

Conclusion

Based on the comparison of the indications for use, technical characteristics and performance, we find that the Difiney Anti Snoring Device is substantially equivalent to the predicate SnoreRx with 510(K) number K170285.