October 22, 2025

Dcstar Inc
Emma Chen
Official Correspondent
228 Park Ave S 30327
New York, New York 10003

Re: K251628
Trade/Device Name: Mandibular Advancement 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: October 9, 2025
Received: October 9, 2025

Dear Emma 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,

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)*
K251628

Device Name
Mandibular Advancement Device

Indications for Use *(Describe)*
The Mandibular Advancement Device is designed to advance the user's lower jaw and maintain this position during use, opening the airway to reduce snoring during sleep. It is intended for adults with 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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

Type of submission

Traditional

Date prepared

2025/10/09

Submitter's Information

Company: DCSTAR INC

Address: 228 PARK AVE S 30327, NEW YORK, NY, UNITED STATES, 10003

Submitter: Emma Chen

Telephone: +1 (650) 672-9428

Email: compliance@complianceglobe.com

Device Information

Device name: Mandibular Advancement Device

Model: L07

Regulation name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea

Production code: LRK

Regulation number: 21 CFR 872.5570

Classification: Class II

Predicate Device Information

510(k) Number: K170825

Manufacturer: Apnea Sciences Corporation

Device Name: SnoreRx

Device Class: Class II

Product Code: LRK

Regulation Number: 21 CFR 872.5570

Indications for use

The Mandibular Advancement Device is designed to advance the user's lower jaw and maintain this position during use, opening the airway to reduce snoring during sleep. It is intended for adults with at least 18 years old.

Device Description

The L07 Mandibular Advancement Device is an intraoral device that is used to maintain the lower jaw in a forward position to increase pharyngeal space so as to improve the ability to exchange air and decrease air turbulence, a causative factor in snoring.

The L07 Mandibular Advancement Device include three types: Type A, Type B, Type C. Each type includes one upper tray and one lower tray. The upper tray of these three types are the same, while they are only different in lower tray. By combining upper tray with different lower tray, the device can be used for advancing lower jaw from 0mm to 6mm.

Substantial Equivalence Discussion

The table below is the comparison of subject device and predicate device:

Table 1 Substantial equivalence comparison

Item	Subject Device	Predicate Device	Remark
Device Name	Mandibular Advancement Device	SnoreRx	-
Model	L07	/	-
Product Code	LRK	LRK	-
Regulation No.	21 CFR 872.5570	21 CFR 872.5570	-
Classification Name	Intraoral Device for Snoring and Obstructive Sleep Apnea	Intraoral Device for Snoring and Obstructive Sleep Apnea	-
Technological Features	Mandibular repositioning device that advances the lower jaw to increase pharyngeal space.	Mandibular repositioning device that advances the lower jaw to increase pharyngeal space.	Same
Intended Use	Intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring. Device is intended for Over The-Counter use.	Intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring. Device is intended for Over The-Counter use.	Same
Material	-Polypropylene -Ethylene vinyl acetate copolymer	-Polycarbonate resin -Ethylene vinyl acetate copolymer	Similar The hard outer shell of predicate device is made of Polycarbonate, while the hard outer shell of subject device is made of Polypropylene.

			Both material are common plastic. This difference won't raise any safety and effectiveness issue.
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 6 mm -Reusable	-Custom-fitted intraoral device -Repositions mandible anteriorly up to 6 mm -Reusable	Same
Sterility	Non-sterile	Non-sterile	Same
Biocompatibility	ISO 10993: Cytotoxicity Irritation Sensitization	ISO 10993: Cytotoxicity Irritation Sensitization	Same

Performance Testing - Clinical

Not Applicable

Performance Testing - Animal

Not Applicable

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

The material were test for cytotoxicity, irritation, and sensitization. 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.

ASTMD 792-20 for Density.

Conclusion

Based on the comparison of the indications for use, technical characteristics and performance, we find that the L07 Mandibular Advancement Device is substantially equivalent to the predicate SnoreRx with 510(K) number K170285.