August 27, 2026

Ram.Shaw Pte., Ltd.
% Emma Chen
Applicant/Sponsor
Ram.Shaw Pte. , Ltd.
120 Robinson Rd., #13-01, Singapore 068913
SINGAPORE

Re: K262104
Trade/Device Name: Anti Snoring Mouthpiece
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: August 6, 2026
Received: August 7, 2026

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 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,

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)*
K262104

Device Name
Anti Snoring Mouthpiece (L09-BB, L09-PP, L09-TB, L09-BT, L09-TP, L09-PT, L09-TT)

Indications for Use *(Describe)*
The anti-snoring mouthpiece is intended to reposition the lower jaw during sleep to help maintain an open airway and reduce snoring in adults aged 18 years or older.
The device is intended for over-the-counter home use.

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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K262104 - 510(k) Summary

Submitter's Information

Company: RAM.SHAW PTE.LTD

Address: 120 ROBINSON ROAD, #13-01, SINGAPORE 068913

Submitter: Emma Chen

Email: compliance@complianceglobe.com

Date: August 25, 2026

Device Information

Trade Name: Anti Snoring Mouthpiece

Common Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.

Classification Name: Device, Anti-Snoring

Model: L09-BB, L09-PP, L09-TB, L09-BT, L09-TP, L09-PT, L09-TT

Size: S and L

Device Class: Class II

Product code: LRK, LQZ

Regulation number: 21 CFR 872.5570

Predicate Device Information

510(k) Number: K253845 Manufacturer:

Manufacturer: RAM.SHAW PTE. LTD

Device Name: Anti Snoring Mouthpiece

Model: L08-BP, L08-PT, L08-BT, L08-TP, L08-TB, L08-PB

Size: S and L

Device Class: Class II

Product Code: LRK

Regulation Number: 21 CFR 872.5570

Indications For Use

The anti-snoring mouthpiece is intended to reposition the lower jaw during sleep to

help maintain an open airway and reduce snoring in adults aged 18 years or older. The device is intended for over-the-counter home use.

Device Description

L09 series is a thermoforming device to reduce snoring. The device works by putting into the mouth and pulling the lower jaw forward.

The L09 series relies on relative length difference of two connection ports to realize mandibular advancement. For example, when the ports on the upper and lower trays are equal in length, the forward displacement of the mandible is 0 mm. By extending the connection port of the lower tray by 6 mm, a fixed 6 mm forward displacement of the lower dental arch is achieved.

By selecting appropriate configuration and using the “Boil-and-Bite” method, users can customize the fit to their dentition.

Substantial Equivalence Discussion

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

Table 1 Substantial equivalence comparison

Item	Subject Device – K262104	Predicate Device – K253845	Remark
Device Name	Anti Snoring Mouthpiece	Anti Snoring Mouthpiece	-
Model	L09-BB, L09-PP, L09-TB, L09-BT, L09-TP, L09-PT, L09-TT	L08-BP, L08-PT, L08-BT, L08-TP, L08-TB, L08-PB	-
Size	S and L	S and L	Same
Product Code	LRK, LQZ	LRK	Same
Regulation No.	21 CFR 872.5570	21 CFR 872.5570	Same
Classification Name	Intraoral Device for Snoring and Obstructive Sleep Apnea	Intraoral Device for Snoring and Obstructive Sleep Apnea	Same
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	-Polypropylene -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 6 mm -Reusable	-Custom-fitted intraoral device -Repositions mandible anteriorly up to 6 mm -Reusable	Same
Method used to manage the mandibular advancement	Relies on relative length difference of two connection ports.	Relies on the relative location of lower protrusion and upper protrusion.	Different Both methods can help realize 6 mm mandibular advancement. This difference won't alter the effectiveness of device and introduce additional risk.
Sterility	Non-sterile	Non-sterile	Same
Biocompatibility	ISO 10993: Cytotoxicity Irritation Sensitization	ISO 10993: Cytotoxicity Irritation Sensitization	Same

The subject device - L09 series is substantially equivalent to the predicate device -L08 series:

a. They have the same intended use
b. They have the similar technological characteristics
c. The subject device is effective and safe as the predicate device

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:

1) Biocompatibility

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" and device-specific guidance.

2) 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.

3) Other aspect

The reprocessing method, shelf use and use life is verified through cleaning method validation testing, shelf use/durability testing, respectively.

Conclusion

Based on the above information, we can conclude that the L09 series Anti Snoring Mouthpiece is substantially equivalent to the predicate L08 series Anti Snoring Mouthpiece.