October 3, 2025

Dongguan Yiyao Science & Technology Development Co., Ltd.
℅ Ivy Wang
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.,
Shanghai 200122, CHINA

Re: K250028
Trade/Device Name: Anti Snore 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
Dated: September 3, 2025
Received: September 3, 2025

Dear Ivy Wang :

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

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DHT1B: Division of Dental and
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250028

Device Name

Anti Snore Mouthpiece (TD-02, TD-03)

Indications for Use *(Describe)*

Anti snore mouthpiece is intended as an aid in the reduction of snoring for adults 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

K250028

Prepared date: 2025-09-25

A. Applicant:

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B. Device:

Trade Name: Anti snore mouthpiece
Model: TD-02, TD-03
Common Name: Anti-snoring Device

Regulatory Information
Classification Name: Device, Anti-Snoring
Regulation Number: 21 CFR 872.5570
Product Code: LRK
Device Class: 2
Review Panel: Dental

C. Predicate device:

510(k) Number: K220688
Trade Name: SilentZPro 2.0
Manufacturer: Shinrin-Yoku Traders LLC

D. Indications for use of the device:

Anti snore mouthpiece is intended as an aid in the reduction of snoring for adults at least 18 years old.

E. Device Description:

Anti snore mouthpiece is an intraoral device composed of a maxillary and mandibular tray assembled to position the mandible forward relative to the maxilla to increase users' pharyngeal space and improve the ability to exchange air and decreases air turbulence, a causative factor in snoring.

F. Comparison with predicate device

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Result
510K number	K250028	K220688	-
Model name	Anti Snore Mouthpiece	SilentZPro 2.0	-
Classification	2	2	Same
Regulation	21 CFR 872.5570	21 CFR 872.5570	Same
Product code	LRK	LRK	Same
Indications for use	Anti snore mouthpiece is intended as an aid in the reduction of snoring for adults at least 18 years old.	SilentZPro 2.0 is intended as an aid in the reduction of snoring for adults at least 18 years old.	Same
OTC use	Yes	Yes	Same
Target	Adults 18 and older	Adults 18 and older	Same
Environment	During sleep, at home	Durin sleep, at home	Same
Mechanism of action	Mandibular repositioning device (MDR) that advances the lower jaw to increase pharyngeal space and alleviate snoring	Mandibular repositioning device (MDR) that advances the lower jaw to increase pharyngeal space and alleviate	Same
Technological characteristics	Flexible, moldable guard used as a barrier between teeth.	Flexible, moldable guard used as a barrier between teeth.	Same
Placement of device	In the mouth, on the lower and upper jaws	In the mouth, on the lower and upper jaws	Same
Preparation / Set-up	Squeeze mouthpiece in a 'C position and adjust. Mold tray Mold the trays to the user's mouth.	Squeeze mouthpiece in a 'C' position and adjust. Mold tray Mold the trays to the user's mouth.	Same

Design	Custom-fitted intraoral device using a “boil and bite” approach and thermal setting (heat sensitive) resins. Molded to the entire upper and lower arch of teeth. Consists of an upper and lower tray. Outer shell provides with structural support and inner shell is lined with softer material that is heat sensitive and thus	Custom-fitted intraoral device using a “boil and bite” approach and thermal setting (heat sensitive) resins. Molded to the entire upper and lower arch of teeth. Consists of an upper and lower tray. Outer shell provides with structural support and inner shell is lined with softer material	Same
Adjustments	Adjustable jaw advancement position. Ability to reset the adjustment. The upper and lower trays are adjustable increments up to 6mm for use comfort.	Adjustable jaw advancement position. Adjustably positions the mandible forward in 3 positions, 4mm apart anteriorly, while maintaining a 9mm inferior placement for user comfort.	Similar The adjustable position numbers and increment length are different with predicated device, which do not raise any new safety and effectiveness concern.
Single Patient/ Reusable	Single user, reusable. Clean/rinse daily with toothbrush and toothpaste or with effervescent oral device cleaning tablets. Deep clean once every three days. Non-sterile.	Single user, reusable. Non-sterile. Requires daily cleaning, and reusable with a life use of no more than 30 days.	Different Both are required daily clean. This difference do not raise new safety or effectiveness concern.
Material	Ethylene-vinyl acetate copolymer (EVA) Polycarbonate (PC)	Polycarbonates (PC); Ethylene-vinyl acetate copolymer resin (EVA)	Same
Biocompatibility	Assessment conducted for testing for prolonged mucosal surface contact in accordance with ISO 10993-1.	Assessment conducted for testing for prolonged mucosal surface contact in accordance with ISO 10993-1.	Same

G. Non-Clinical Test Conclusion

Bench testing has demonstrated that the device is in compliance with pertinent standards and

specifications, the expectations of the dental community and the product labeling. Performance testing was performed to the proposed device including hardness, water absorption, melting point, tensile strength & elongation testing, forming time and movement measurement testing to demonstrate its effectiveness, which supports its substantial equivalence to the predicate device.

Additionally, as per "Intraoral Devices for Snoring and/or Obstructive Sleep Apnea- Class II Special Controls Guidance Document for Industry and FDA", tests for genotoxicity (ISO 10993-3), tests for in vitro Toxicity (ISO 10993-5), tests for irritation (ISO 10993-23) , tests for systemic toxicity (ISO 10993-11) and tests for skin sensitization (ISO 10993-10) were conducted on the anti snore mouthpiece.
The results of the testing met the requirements of the study protocols and the material is considered non-toxic, non-sensitizing and is not an intracutaneous irritant. The results of the studies further support a determination of substantial equivalence to the predicate.

H. Clinical Test Conclusion
No clinical study is included in this submission.

I. Conclusion
The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K220688.