December 5, 2025

QuietLab, LLC
% Eileen Heller
Final Reviewer
Beanstock Consulting
8885 Rio San Diego Dr. #237
San Diego, California 92108

Re: K253868
Trade/Device Name: QuietLab Pro
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: November 25, 2025
Received: December 3, 2025

Dear Eileen Heller:

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
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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.

Submission Number *(if known)*

K253868

Device Name

QuietLab Pro

Indications for Use *(Describe)*

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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K253868

510(k) Summary

Prepared on: 2025-11-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	QuietLab LLC
Applicant Address	447 Broadway 2530, 2nd Floor New York NY 10013 United States
Applicant Contact Telephone	+39 3519657679
Applicant Contact	Mr. Pietro Candriella
Applicant Contact Email	pietro@tryquietlab.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	QuietLab Pro
Common Name	QuietLab Pro
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
K180124	ZQuiet OTC	LRK
K213088	ZQuiet Advance	LRK
K201719	Vital Sleep	LRK
K121761	SomnoGuard SP Soft	LRK

Device Description Summary

21 CFR 807.92(a)(4)

The QuietLab Pro Anti-Snoring Mouthpiece is a reusable, over-the-counter oral appliance intended to reduce or eliminate snoring by gently repositioning the lower jaw to maintain an open upper airway during sleep. The device achieves this effect through a precision-adjustable mandibular advancement mechanism that minimizes airway collapse and reduces tissue vibration—the primary cause of snoring.

Scientific Basis and Mechanism of Action:
Snoring typically occurs when the muscles around the throat relax during sleep—especially during REM—causing a partial collapse of the airway. As air moves through this narrowed passage, it vibrates the soft tissues, producing the characteristic sound of snoring.
The QuietLab Pro addresses this by:
- Advancing the lower jaw (mandible) slightly forward using a precision-fit tray and hinge system.
- Increasing pharyngeal space to prevent airway collapse.
- Promoting steady airflow and reducing soft tissue vibration during sleep.

Device Design and Key Performance Characteristics:
The QuietLab Pro is comprised of three primary components, designed for comfort, adjustability, and durability:

1. Central Part - Structural Component
o Thermoplastic Polyurethane for flexible hinge zones.
o Provides structural support, maintains upper/lower tray alignment, and enables lateral jaw movement during sleep.
2. Central Part – Hard Inserts & Attachment Pins (4-Pin Diamond-Shaped Sliding Mechanism)
o Made of Polycarbonate (PC) for rigidity
o Offers incremental, repeatable adjustment to tailor the mandibular position to the user's anatomy.
o Prevents unintentional shifting during use, improving comfort and treatment consistency.
3. Upper and Lower Trays (Anatomical Trays)
o Fabricated from Thermoplastic Elastomer
o Anatomically contoured to fit over dental arches without molding.
o The lower tray allows for up to 9 mm of mandibular advancement via a 25-position micro-adjustment system.

Material Composition:
All components are made of biocompatible, medical-grade materials tested for prolonged mucosal contact (per ISO 10993-1):
• PC (Polycarbonate) – Provides strength and stability.
• TPU (Thermoplastic Polyurethane) – Allows for flexibility at hinge and contact points.
• TPE (Thermoplastic Elastomer) – Ensures soft tissue compatibility and user comfort.
The device is manufactured in an ISO-certified facility under strict quality controls and is compliant with RoHS material safety standards.

The carrying-case material is indirect patient contact only.

Physical Properties:
• Non-sterile, reusable device intended for single-patient use.
• Designed for home use during sleep.
• Accommodates diverse dental anatomies through flexible materials and an Adaptive Fit system.
• Lightweight, with integrated grooves to promote airflow and minimize saliva buildup.

Function and Adjustability:
• Upper Tray: Provides upper jaw stabilization.
• Lower Tray: Delivers adjustable mandibular advancement.
• Adjustment Range: Up to 9 mm total advancement with fine control.
• Custom Fit: No boiling or molding required; adjustment is tool-free and user-controlled.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Intended as an aid in the reduction of snoring for adults at least 18 years old.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use for the subject device, QuietLab Pro, are: Intended as an aid in the reduction of snoring for adults at least 18 years old.

This is identical to the indications for use of the identified predicate devices, including:
ZQuiet OTC (K180124)
ZQuiet Advance (K213088)
Vital Sleep (K201719)
SomnoGuard SP Soft (K121761).

There are no differences in the intended therapeutic use, patient population, or environment of use between the subject device and the predicates. All are over-the-counter, intraoral appliances used during sleep to reduce snoring in adults. The mechanism—mandibular advancement to alleviate airway obstruction—remains consistent.Thus, the QuietLab Pro does not introduce a new intended use under 21 CFR 807.92(a)(5).

Technological Comparison

21 CFR 807.92(a)(6)

The QuietLab Pro shares the same fundamental technological characteristics as the predicate devices.

It is a reusable, OTC intraoral anti-snoring mouthpiece that:Advances the mandible forward to increase pharyngeal space,Operates via mechanical means (no electronics or external energy sources),Is used during sleep in the home environment, andContacts the oral mucosa for a prolonged duration.

Technological Differences:
While similar in principle of operation and classification, QuietLab Pro incorporates the following enhanced technological features:

Expanded Adjustment Range: Offers up to 9 mm of mandibular advancement using a 25-position micro-adjustment mechanism. This is within the 10 mm range of reference device SomnoGuard SP Soft (K121761).

Incremental Precision: Enables fine-tuned advancement in small, repeatable increments, improving patient customization and comfort.

Material Composition: Constructed from biocompatible medical-grade PC (Polycarbonate), TPU (Thermoplastic Polyurethane), and TPE (Thermoplastic Elastomer)—materials chosen for strength, flexibility, and oral safety. All materials meet ISO 10993-1 testing for acute system toxicity, cytotoxicity, sensitization, and irritation.

No Boil-and-Bite Fitment: Unlike some predicates (e.g., Vital Sleep), the device does not require thermal molding. Instead, trays are anatomically pre-contoured and rely on user-controlled adjustment.
Usability Validated: The full 0–9 mm range and adjustability mechanism were evaluated during a 30-subject usability study, confirming safe and effective self-use without clinical supervision.

These differences enhance the usability, precision, and comfort of the device but do not raise new questions of safety or effectiveness. All features are consistent with the performance of legally marketed predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Usability validation was conducted with 31 users per IEC 62366.

The device is a long-term mucosal-contacting intraoral appliance. The following biocompatibility tests were conducted in alignment with ISO 10993-1:
• Acute Systemic Toxicity
• Cytotoxicity (Extract and Indirect)
• Oral Mucosa Irritation
• Skin Sensitization

Not Applicable.

Based on the data provided, including usability validation results, risk mitigations, and labeling information, the QuietLab Pro mouthpiece is found to be substantially equivalent to its predicate device. The usability validation demonstrated that intended users were able to use the device safely and effectively in the intended use environment without new questions of safety or effectiveness. Observed use errors were infrequent, minor in nature, and appropriately mitigated through clear labeling, instructions, and risk controls. The device does not raise different technological characteristics or performance issues compared to the predicate. Refer Bench Testing section of the eStar for plans and reports.

The device is a long-term mucosal-contacting intraoral appliance. The following biocompatibility tests were conducted in alignment with ISO 10993-1:
• Acute Systemic Toxicity
• Cytotoxicity (Extract and Indirect)
• Oral Mucosa Irritation
• Skin Sensitization

These results demonstrate that all endpoints applicable to a mucosal-contacting device have been addressed. No additional endpoints (e.g., subchronic toxicity or genotoxicity) were indicated due to the absence of novel materials or coatings. Refer to Biocompatibility Reports and Documentation section of the eStar for plans and reports.

Clinical performance data was not submitted as the QuietLab Pro is substantially equivalent in design, materials, and intended use to a legally marketed predicate device (510(k) number provided in Substantial Equivalence section). Bench performance testing which included usability validation and biocompatibility testing are sufficient to support safe and effective use under the FDA's least burdensome provisions. Refer Bench Testing section of the eStar for plans and reports.