



April 10, 2026

Shaeferh, LLC
Andy Cheung
Dentist
45 Stuart St.
2501
Boston, Massachusetts 02116

Re: K252942

Trade/Device Name: ShaeferH

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: September 15, 2025

Received: September 15, 2025

Dear Andy Cheung:

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
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252942

?

Please provide the device trade name(s).

?

ShaeferH

Please provide your Indications for Use below.

?

The ShaeferH Oral Appliance is indicated for the treatment of mild to moderate obstructive sleep apnea (OSA) and/or snoring in adult patients, 18 years of age or older.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	ShaeferH LLC
Applicant Address	45 Stuart St 2501 Boston MA 02116 United States
Applicant Contact Telephone	415-672-8286
Applicant Contact	Dr. Andy Cheung
Applicant Contact Email	andycheungdmd@gmail.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	ShaeferH
Common Name	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
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
K203606	Serena Sleep Block Mandibular Advancement	LRK

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The ShaeferH Oral Sleep Appliance is a prescription, custom-fabricated, single-patient, reusable intraoral mandibular advancement device intended for use during sleep.

The device is designed as a monoblock oral appliance that positions the mandible anteriorly relative to the maxilla to help maintain upper airway patency during sleep. Mandibular advancement is established through clinician-directed fitting and adjustment performed outside of patient use. Once fitted, the device passively maintains the selected mandibular position during use.

The ShaeferH Oral Sleep Appliance is a non-powered device and does not contain electrical components, software, batteries, wireless technology, or active heating elements. The device is fabricated from medical-grade polymeric materials suitable for prolonged intraoral mucosal contact and is intended for single-patient use in a home sleep environment.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The ShaeferH Oral Appliance is indicated for the treatment of mild to moderate obstructive sleep apnea (OSA) and/or snoring in adult patients, 18 years of age or older.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use of the ShaeferH Oral Appliance are the same as those of the identified predicate device, as both are intended for the reduction or alleviation of mild to moderate obstructive sleep apnea (OSA) and/or snoring by repositioning the mandible during sleep.

The ShaeferH Oral Appliance incorporates a clinician-established mandibular positioning interface that represents an alternative design approach for achieving mandibular repositioning. This design difference does not alter the intended therapeutic purpose of the device and does not constitute a new intended use.

The ShaeferH Oral Appliance has technological characteristics that are similar to those of the identified predicate device(s) in terms of overall design, principle of operation, and intended function. Both the subject device and the predicate device(s) are non-powered, intraoral mandibular advancement devices that reposition the mandible anteriorly during sleep to maintain upper airway patency. The subject device and the predicate device(s) share the same fundamental principle of operation, relying on mechanical mandibular repositioning without the use of electronics, software, or external energy sources. Both devices are custom-fabricated intraoral appliances intended for single-patient use and are retained through adaptation to the patient's oral anatomy.

The ShaeferH Oral Appliance incorporates a clinician-directed titration mechanism that differs in implementation from that of the predicate device(s) but serves the same functional purpose of setting and maintaining mandibular advancement. This difference represents an alternative technological approach to achieving mandibular repositioning and does not alter the device's principle of operation, clinical function, or intended patient population.

A detailed comparison of technological characteristics, including design features, materials (at a non-confidential level), adjustment mechanisms, and indications for use, is provided in the attached Substantial Equivalence Comparison Table

Non-Clinical and/or Clinical Tests Summary & Conclusions

No device-level nonclinical mechanical performance testing was conducted for this submission.

The ShaeferH Oral Sleep Appliance is a passive, monoblock intraoral mandibular advancement device without articulated joints, detachable components, mechanical connectors, dynamic adjustment mechanisms, or powered features. Mandibular positioning is statically established during fabrication or fitting and remains fixed during patient use.

The device is fabricated from a thermoplastic polymer that is chemically equivalent to ethylene-vinyl acetate (EVA), supported by legally marketed reference device K121365, and incorporates a thermo-responsive liner material (ThermAcryl), a Class I, 510(k)-exempt dental material used strictly in accordance with the manufacturer's instructions.

The fabrication process does not introduce solvents, primers, adhesives, or chemical bonding agents, and does not introduce detachable joints, hinges, or user-actuated adjustment mechanisms.

Based on comparison to the primary predicate device (K203606), and the absence of new mechanical principles or novel structural features, the subject device does not introduce technological characteristics that would require additional device-specific mechanical performance testing beyond comparison to legally marketed devices of this type.

Not Applicable.

No clinical testing was submitted, referenced, or relied upon to support a determination of substantial equivalence. The subject device is a passive intraoral mandibular advancement appliance, and substantial equivalence was evaluated based on intended use, technological characteristics, materials, and principle of operation relative to legally marketed predicate devices of this type.

No nonclinical or clinical performance testing was conducted for this submission.

The ShaeferH Oral Sleep Appliance is a passive, non-powered, monoblock intraoral mandibular advancement device that operates through static mandibular repositioning established during fabrication or fitting.

The technological characteristics, materials, and principle of operation are consistent with those of legally marketed intraoral mandibular advancement appliances, including the primary predicate device (K203606).

Based on material equivalence, passive configuration, and comparison to legally marketed devices of this type, the subject device does not introduce new questions of safety or effectiveness.