September 17, 2025

The Tmj Clinic PC
John Summer
Dentist, President
833 SW 11th Ave.
810
Portland, Oregon 97205

Re: K243752
Trade/Device Name: Double Tube Herbst Appliance
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: December 5, 2024
Received: December 5, 2024

Dear John Summer:

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
ENT Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243752

Device Name

double tube herbst appliance

Indications for Use *(Describe)*

to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K243752

510(k) Summary

Prepared on: 2025-09-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	the tmj clinic PC
Applicant Address	833 SW 11th Ave. # 810 portland or 97205 United States
Applicant Contact Telephone	503-329-1810
Applicant Contact	Dr. john summer
Applicant Contact Email	john.summer03@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	double tube herbst appliance
Common Name	double tube herbst appliance
Classification Name	class 2 special controls
Regulation Number	21 CFR 872.5570
Product Code(s)	lrk, 872.5570

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K130130	AT G /M-O SA APPL ANCE	lrk
K222127	soft palate elevator, reference device	LQZ
K143244	Panthera Anti-Snoring Device, reference device	LRK

Device Description Summary

21 CFR 807.92(a)(4)

SUBMITTER AND CONTACT: John Summer, 833 SW 11th Ave # 810, Portland OR 97205
Phone: 503-241-7353 fax: 503-525-2966 Email:john.summer03@gmail.com
DEVICE NAME: DOUBLE TUBE HERBST APPLIANCE
REGULATION NUMBER: 21 CFR 872.5570
CLASSIFICATION: CLASS 2, SPECIAL CONTROLS
GUIDANCE DOCUMENT: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea
SCOPE – Intraoral devices for snoring and/or obstructive sleep apnea.
PRODUCT CODES - LRK and LQZ

MATERIALS/BIOCOMPATIBILITY - Materials include sheet acrylic, cold cure acrylic resin, and stainless steel, - the exact same materials as are in the predicates, in about the same proportions. The biocompatibility of these materials in the intended use environment poses no unacceptable risks.

NARRATIVE DESCRIPTION - The Double Tube Herbst appliance consists of upper and lower base appliances connected on each side by a telescopic apparatus that advances the mandible. Each telescopic apparatus is loosely but securely attached to wire loops formed at the ends of retentive anchors embedded in the acrylic on the outer (buccal) surfaces of the upper and lower base appliances. A telescopic apparatus consists of a double tube telescopic assembly that is attached to the back end of the upper wire loop; and a rod that is attached to the front end of the lower wire loop. The double tube telescopic assembly consists of a short internally threaded tube

welded in parallel onto the back of a long straight tube in which the rod slides. The short internally threaded tube is adjustably attached to the back end of the upper wire loop by engaging the externally threaded lower end of a connector, the upper end of which ends in a helix that is twisted around the upper wire loop. The rod that slides in and out of the long tube is loosely but securely attached to the wire loop on the front end of the lower retentive anchor. The lengths of the telescopic assemblies can be adjusted in 1/2 mm increments along a range of 15 mm by disengaging the telescopic components, rotating the double tube assembly around the connecting arm, and sliding the rod back into the long tube to lock in the adjustment.

INTENDED USE – The Double Tube Herbst appliance is worn while sleeping to keep the mandible in a forward position prescribed by the treating dentist to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults. The customized appliance is inserted and removed by the patients every night, and it is adjusted by the prescribing dentist.

RISKS – The risk of causing damage to TMJs and teeth is mitigated by the unrestricted lateral range of motion and the easy adjustability of the lengths of the telescopic assemblies without tools coupled with the patient instructions to return to the treating dentist to have it adjusted backward ("walkback") as soon as symptoms arise. The risk of loosening or flaring of the lower teeth or general tooth movement is mitigated in Herbst appliances by full arch coverage which distributes the forces generated by mandibular advancement all around the upper and lower dental arches and thereby prevents excessive force from being delivered to one or more teeth. The risk of dislodging a part that could cause choking or aspiration is mitigated by the retentive design of the anchors, the minimal number of parts, and their secure connections.

PERFORMANCE DATA – Bench testing was performed to assess the forces that the components are able to withstand and to compare them to the forces that the primary predicate are able to withstand.

PRIMARY PREDICATE DEVICE– is the ATG/SM-OSA APPLIANCE, K130130, cleared in August 2013 and currently widely available. It has the same basic technological characteristics, indications for use, intended use, and mode of action as the subject device. It differs from the subject device in the methodology for attaching the telescopic components to the base appliance and the methodology for adjusting the lengths of the telescopic assemblies.

REFERENCE DEVICES - Panthera Anti-Snoring Device, K 143244 for recommended maximum advancement. Soft palate elevator K222127 for identical chemical composition for biocompatibility.

COMPARATIVE SAFETY - Compared to the predicate, the subject device poses the same risk of causing TMJ or tooth damage due to the unrestricted lateral range of mandibular movement, the same risk of damage to mucous membranes lining the cheeks and lips due to a lower profile, the same risk of a part breaking free and causing choking or aspiration due to the number of parts and their secure connections, the same risk of toxic leaching due to the same materials and use conditions, and about the same risks of misuse and abuse.

COMPARATIVE EFFECTIVENESS – The subject device has the same effectiveness as the predicate, because it has the same mode of action.

RISK/BENEFIT ANALYSIS – The potential benefits are significant, because obstructive sleep apnea causes so many serious health problems. The risks generally involve the dentition and its supporting tissues, which must withstand the forces generated by the treatment on a long-term basis.

CONCLUSION The Double Tube Herbst Appliance is similar in intended use and technological characteristics as the predicate device, - ATG/SM-OSA Appliance (K130130). Based on the performance testing, the Double Tube Herbst Appliance is shown to be substanially equivalent.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

to reduce nighttime snoring and mild to moderate obstructive sleep apnea in adults

Indications for Use Comparison

21 CFR 807.92(a)(5)

same indications for use

Technological Comparison

21 CFR 807.92(a)(6)

The subject and predicate devices have the same intended use, indications for use, mode of action, basic technological characteristics, performance records, and user interface. They differ in the methodology for attaching the telescopic components to the base appliances and the methodology for adjusting the effective lengths of the telescopic assemblies. These differences from the predicate are designed to increase both safety and effectiveness in the subject device. They are discussed in detail in the attachment below.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

physical properties testing was performed by Engineering Materials

Lab Not Applicable