November 14, 2023

Prismatik Dentalcraft, Inc
Jiahe Li
Senior Regulatory Affairs Specialist
2144 Michelson Drive
Irvine, California 92612

Re: K233434
Trade/Device Name: Silent Nite® Sleep Appliance with the Glidewell Hinge™ (SNGLHG)
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: October 12, 2023
Received: October 13, 2023

Dear Jiahe Li:

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.

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

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)*

K233434

Device Name

Silent Nite® Sleep Appliance with the Glidewell Hinge™ (SNGLHG)

Indications for Use *(Describe)*

Silent Nite Sleep Appliance with the Glidewell Hinge is indicated to reduce snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older. It is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K233434

510(k) Summary

Date Prepared: Nov 13, 2023

Contact Details (21 CFR 807.92(a)(1))

Applicant Name: Prismatik Dentalcraft, Inc.

Applicant Address: 2144 Michelson Drive Irvine CA 92612 United States

Applicant Contact Telephone: 949-222-3516

Applicant Contact: Mr. Jiahe Li

Applicant Contact Email: jiahe.li@glidewelldental.com

Device Name (21 CFR 807.92(a)(2))

Device Trade Name: Silent Nite® Sleep Appliance with the Glidewell Hinge™

Common Name: Anti-snoring device

Classification Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea

Regulation Number: 872.5570

Product Code: LRK

Legally Marketed Predicate Device (21 CFR 807.92(a)(3))

Predicate 510(k) #: K210694

Predicate Trade Name: Silent Nite Sleep Appliance with the Glidewell Hinge

Product Code: LRK

Device Description Summary (21 CFR 807.92(a)(4))

The subject device, Silent Nite® Sleep Appliance with the Glidewell Hinge™, is a mandibular advancement device (MAD). It holds the mandible in a protrusive position to increase the patient's ability to exchange air and decrease air turbulence, thus improving airflow during sleep.

The subject device, Silent Nite® Sleep Appliance with the Glidewell Hinge™, consists of upper and lower trays, and an engaging mechanism made of stainless-steel, which is the Glidewell hinge.

Optional orthodontic (elastic) bands are provided as accessories. The trays consist of a soft polyurethane inner layer that provides patient comfort and a hard polyester outer layer for durability. The hinge is adjustable by turning an inner adjustment screw with a hex driver, enabling the amount of mandibular advancement prescribed by the clinician. The design allows for the advancement of the mandible to be adjusted (increased or decreased) in 0.25 mm increments up to 10 mm.

The subject device, Silent Nite® Sleep Appliance with the Glidewell Hinge™, is customized to conform to the patient's upper and lower dentition based on the clinician's prescription. Upon receipt of the prescription, models for the trays are made and used during the thermoforming fabrication of the upper and lower trays.

Intended Use/Indications for Use (21 CFR 807.92(a)(5))

Silent Nite Sleep Appliance with the Glidewell Hinge is indicated to reduce snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older. It is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.

Indications for Use Comparison (21 CFR 807.92(a)(5))

The subject device, Silent Nite® Sleep Appliance with the Glidewell Hinge™, has the same indications for use as the predicate/original device, Silent Nite® Sleep Appliance with the Glidewell Hinge™ (K210694).

Technological Comparison (21 CFR 807.92(a)(6))

The subject device, Silent Nite® Sleep Appliance with the Glidewell Hinge™, is substantially equivalent in technical characteristics to the predicate device, Silent Nite® Sleep Appliance with the Glidewell Hinge™ (K210694) in terms of overall design, material and other key technological features.

The subject device, Silent Nite® Sleep Appliance with the Glidewell Hinge™, is the same in terms of overall design as the predicate device, Silent Nite® Sleep Appliance with the Glidewell Hinge™ (K210694). The device consists of a pair of dual-layered thermoplastic trays and an adjustable hinge made of stainless steel. The device is designed to hold the mandible in a protrusive position with the hinge mechanism to increase the patient's ability to exchange air and decrease air turbulence, thus improving airflow during sleep for treatment of sleep disordered breathing conditions such as snoring, gasping, and mild to moderate obstructive sleep apnea in adults 18 years of age or older. The hinge design uses a stainless-steel rod and tube mechanism to position the mandible forward. The hinge is adjustable by turning an inner adjustment screw with a hex driver, enabling the amount of mandibular advancement prescribed by the clinician.

The subject device, Silent Nite® Sleep Appliance with the Glidewell Hinge™, is the same in terms of material composition as the predicate device, Silent Nite® Sleep Appliance with the Glidewell Hinge™ (K210694). The upper and lower trays are fabricated using the same biocompatible dual-layered thermoplastic material. The engaging mechanism, Glidewell Hinge, is made of the same biocompatible medical grade stainless steel bars. All material in the final finished state of the subject device, Silent Nite® Sleep Appliance with the Glidewell Hinge™, are the same as the predicate device, Silent Nite® Sleep Appliance with the Glidewell Hinge™ (K210694), in its final finished state.

The subject device, Silent Nite® Sleep Appliance with the Glidewell Hinge™, is substantially equivalent in terms of key technological features to the predicate device, Silent Nite® Sleep Appliance with the Glidewell Hinge™ (K210694). Both devices have the same mandibular advancement capacity of maximum 10mm at 0.25mm increment. The subject device is an improved version of the predicate device, with only modifications in the Glidewell hinge components. The new streamlined design has better retention to the trays and has smoother and more secure advancement adjustment. The changes in hinge design do not raise different questions of safety and effectiveness and were addressed with routine verification testing submitted in the 510(k).

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

Design verification according to Silent Nite with Glidewell Hinge Design Verification Protocol were conducted by Prismatik Dentalcraft, Inc. The tests conducted are listed below.

- Maximum and Incremental adjustment for the hinge
- Retention strength of the hinge
- Laser weld inspection
- Telescopic rod movement test

The test samples were made using the standard fabrication process and QC process for Silent Nite® Sleep Appliance with the Glidewell Hinge™ to ensure that the test samples meet the following criterial for the finished device:

- Hinge placement/positioning is correct
- Device fits and retains to the model
- Hinge is attached well to the trays
- Device's final finish is smooth and free of roughness or burs

The results of the verification activities confirmed that the design of the subject device, meet all the predetermined criteria according to the design specifications. The results of testing were used to address questions related to substantial equivalence based on differences in technological features between the subject device, Silent Nite® Sleep Appliance with the Glidewell Hinge™, and the predicate device, Silent Nite® Sleep Appliance with the Glidewell Hinge™ (K210694),

by verifying that the modified device met all the design specification requirements, and the design changes were implemented successfully without causing any unexpected issues.