June 16, 2021

Prismatik Dentalcraft, Inc.
% Patsy Trisler
Regulatory Consultant
Qserve Group US, Inc.
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K210694
Trade/Device Name: Silent Nite Sleep Appliance with the Glidewell Hinge
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: May 13, 2021
Received: May 17, 2021

Dear Patsy Trisler:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K210694

Device Name

Silent Nite Sleep Appliance with the Glidewell Hinge

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 patients 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.

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510(k) Summary – K210694

Submitter Name:	Prismatik Dentalcraft, Inc.
Submitter Address:	2144 Michelson Drive Irvine, CA 96212
Contact Person:	Herbert Schoenhoefer Director of RA/QA
Telephone:	949.440.2632
Date Prepared:	May 13, 2021
Device Trade Name:	Silent Nite Sleep Appliance with the Glidewell Hinge
Common Name	Anti-Snoring Device
Classification Name and Number Product Code Regulatory Class	Intraoral devices for snoring and for obstructive sleep apnea 21 CFR 872.5570 LRK II
Primary Predicate Device:	K183270, Silent Nite sl, Prismatik Dentalcraft, Inc. (LRK)
Reference Devices and Product Codes:	Reference #1: K200125, Thermoforming Sheet Materials, Erkodent Erich Kopp GmbH (MQC, KMY) Reference #2: K083209, Acrylic Herbst Splint Appliance, Specialty Appliances Works (LRK)
Indications for Use Statement:	Silent Nite Sleep Appliance with the Glidewell Hinge is indicated to reduce snoring and mild to moderate obstructive sleep apnea (OSA) in patients 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.
Device Description. Mechanism of Action, and Summary of Technological Characteristics	The Silent Nite Sleep Appliance with the Glidewell Hinge is a mandibular advancement device. 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 device consists of upper and lower trays, which are fabricated using a biocompatible dual-layered thermoplastic material, and an engaging mechanism, which is the Glidewell Hinge (biocompatible medical grade stainless steel bars), and band lugs and hooks for attaching the optional orthodontic (elastic) bands, which 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 orthodontic bands accessories are used to aid in holding the mouth closed. The end result, a forward position of the jaw, is the same as the predicate, however, the method of action of the predicate device and subject device are slightly different. Silent Nite Sleep Appliance with the Glidewell Hinge's method of action is identical to the Reference device and both use orthobands. Without orthobands, the patient's mouth can open during sleep which allows the tongue to fall back into the airway. The orthobands help keep the mouth closed to avoid this. With just a slight protrusion, the orthobands can be placed on the provided hooks. More protrusion requires the orthoband to be placed on the forward hook and the band lug.

The device 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.

The difference between the Silent Nite Sleep Appliance with the Glidewell Hinge and the Primary Predicate Silent Nite sl is the mechanism connecting the trays: The new device's stainless steel hinge allows adjustment within the mechanism, while the Predicate's adjustment requires changing the plastic connectors.

This is a non-sterile device, to be used only by the single patient for whom it is custom-designed and is to be worn during sleep.

Device Testing

Laboratory Testing

Verification and validation of the manufacturing process was performed by Prismatik Dentalcraft, Inc.

Verification testing was conducted to assure the following functional attributes of the finished device were correct:

- Mandibular advancement function
- Maximum hinge displacement (mm)
- Hinge placement/positioning

Validation showed that the following were acceptable:

- 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

Biocompatibility

ISO 10993 testing was performed to assess the safety and biocompatibility of the Thermoforming Sheet Materials and documentation was provided in the 510(k) for the Reference device, K200125. The testing showed the material is safe and biocompatible for the intended use "fabrication of orthodontic and dental appliances".

The following biocompatibility testing was conducted according to Good Laboratory Practices and per ISO 10993 on the stainless steel hinge component of the device:

- In vitro Cytotoxicity (Part 5)
- Guinea Pig Maximization Sensitization (Part 10)
- Oral Mucosal Irritation in Hamsters:14 days (Part 10)

The test article met the requirements of each test and is safe and biocompatible for the intended use.

Animal | Human Testing

No animal or human testing are required for this product because it is composed of the same materials, is designed similarly, and is manufactured by method similar to the predicate device.

Comparison to Predicate Device:

Refer to the Comparison Table below for similarities and differences between Silent Nite Sleep Appliance with the Glidewell Hinge and the Primary Predicate device. In summary:

- The intended uses are the same.
- The mechanisms of actions are the same.
- The materials used for the trays are the same as the Predicate and Reference #1.
- The methods used for manufacturing the appliances are similar.
- The materials used for the connector mechanism are different and the design for adjusting the jaw position is different, as follows:

. The technological design of the subject device allows for micro-adjustments of the mandibular position to achieve the needed improvement in airflow during sleep, which is similar to Reference #2, while the Predicate device allows for millimeter incremental adjustment. Reference #2 also includes the optional orthobands like the subject device, but unlike the Predicate.

The design and material differences in the connector mechanism do not raise different questions of safety and effectiveness, and were addressed with standard verification and validation testing submitted in the 510(k).

Substantial Equivalence Conclusion

Based on the documentation presented in the 510(k), as summarized above and the following side-by-side comparison, it can be concluded subject device is substantially equivalent to the predicate device.

Substantial Equivalence Comparison Table

Element	New Device	Primary Predicate	Comparison
Device name: 510(k) #:	Silent Nite Sleep Appliance with the Glidewell Hinge K210694	Silent Nite® sl K183270	N/A
Regulatory Classification: Product Code: Class:	 21 CFR 872.5570 LRK II	 21 CFR 872.5570 LRK II	Same
Submitter:	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Indications for Use:	To reduce snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older. Silent Nite with the Glidewell Hinge is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.	To reduce snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older. Silent Nite® sl is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.	Same
Method of Use:	Single patient use, removable and reusable appliance	Single patient use, removable and reusable appliance	Same
Prescription Use Only:	Yes	Yes	Same
Environment of Use:	In patient's home or in sleep laboratory	In patient's home or in sleep laboratory	Same
DESIGN:			
Rigid Trays	Yes	Yes	Same
Adjustable	Yes	Yes	Same
MATERIALS:			
Trays:	Heat-sensitive impression dual-layer material	Heat-sensitive impression dual-layer material	Same as Primary Predicate and Reference #1
Advancement Mechanism:	Stainless steel rod and tube mechanism to position the mandible forward	Plastic connectors to position the mandible forward	Similar to Primary Predicate and same as Reference #2
STERILITY:	Non-sterile	Non-sterile	Same
BIOCOMPATIBILITY	All materials meet requirements of ISO 10993: • Cytotoxicity • Irritation • Sensitization	All materials meet requirements of ISO 10993: • Cytotoxicity • Irritation • Sensitization	Same