July 17, 2019

Prismatik Dentalcraft, Inc.
Mythili Reguraman
RA/QA Associate
2181 Dupont Dr.
Irvine, California 92612

Re: K183270
Trade/Device Name: Silent Nite sl
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: June 14, 2018
Received: June 17, 2018

Dear Mythili Reguraman:

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,

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

PRISMATIK DENTALCRAFT, INC.

007_Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183270

Device Name
Silent Nite® sl

Indications for Use *(Describe)*
Silent Nite® sl is indicated 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.

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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008_510(k) Summary

This 510(k) summary of substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	2181 Dupont Dr. Irvine, CA 92612
Company Phone	(949) 440-2739
Company Fax	(949) 553-0924
Facility Registration Number:	2031503
Primary Contact Person:	Mythili Reguraman RA/QA Associate
Date Summary Prepared:	June 4, 2019

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Silent Nite® sl
Common Name:	Anti-Snoring Device
Classification Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulation Number:	21 CFR 872.5570
Product Code:	LRK
Device Class:	2
Review Panel:	Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Primary Predicate: OASYS Hinge Appliance™ (K083209)

Reference Predicate Device: SilentNite® (K972424)

D. DEVICE DESCRIPTION

Silent Nite® sl is a mandibular advancement device (MAD) intended to treat snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older who prefer it to CPAP or surgical treatment, or who do not respond to, are not appropriate candidates for, or who fail treatment attempts with CPAP or surgical treatment. Silent Nite® sl holds the mandible in a protrusive position to increase the volume of the nasopharynx and the oropharynx and improves airflow during sleep. It is meant to be worn during sleep by a single patient. It consists of one upper tray, one lower tray, and two connectors and is provided non-sterile.

The trays are patient-specific and conform precisely to the patient's dentition. A biocompatible dual-layered heat sensitive impression material make up the upper and lower trays. The trays consist of a soft polyurethane inner layer that provides patient comfort and a durable hard polyester outer layer. A completely rigid polyester material is necessary for the fabrication of the lower tray when the patient has poor retention.

The maxillary tray is connected to a mandibular tray by two connectors of the same length. Each connector is fixed to the anterior of the maxillary tray and the posterior of the mandibular tray, on the respective right and left buccal sides. The amount of mandibular protrusion is adjusted by varying the length of the connectors. The shorter the connector the more anteriorization. Silent Nite® sl connectors are available in six different lengths (21.0 mm, 22.0 mm, 23.0 mm, 24.0 mm, 25.0 mm, and 26.0 mm) to allow the device to be adjusted up to 6.0 mm, in 1.0 mm increments.

E. INDICATIONS FOR USE

Silent Nite® sl is indicated 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.

F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Refer to the Comparison Table below showing similarities and differences between the primary predicate device, reference predicate device, and subject device.

Table 1 – Comparison between Primary Predicate device, Reference Predicate device, and Subject device

Trade Name	**Subject Device** Silent Nite® sl	**Primary Predicate Device** OASYS Hinge Appliance™	**Reference Predicate Device** SilentNite®	**Comparison**
510(k)	K183270	K083209	K972424	
Regulatory Classification	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	Same as Primary and Reference Predicate Devices
Product Code	LRK	LRK	LRK	Same as Primary and Reference Predicate Devices
Classification	II	II	Unclassified	Same as Primary Predicate Device
Intended Use	Snore Prevention and Treatment of Obstructive Sleep Apnea	Snore Prevention and Treatment of Obstructive Sleep Apnea	Snore Prevention and Treatment of Obstructive Sleep Apnea	Same as Primary and Reference Predicate Devices
Indications for Use	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.	To reduce snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older. The appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.	Refer to Indications for Use statement of K972424.	Same as Primary Predicate Device and Similar to Reference Predicate Device
Method of Use	Removable and reusable intraoral mandibular repositioning device for a single patient.	Removable and reusable intraoral mandibular repositioning device for a single patient.	Removable and reusable intraoral mandibular repositioning device for a single patient.	Same as Primary and Reference Predicate Devices
Prescription Use Only	Yes	Yes	Yes	Same as Primary and Reference Predicate Devices
Target Population	Adult patients 18 years and older	Adult patients 18 years and older	Adult patients 18 years and older	Same as Primary and Reference Predicate Devices
Contraindication	-Patients who have central sleep apnea -Patients who have severe respiratory disorders	-Patients who have central sleep apnea -Patients who have severe respiratory disorders	Temporomandibular Joint (TMJ) dysfunction	Same as Primary Predicate Device and Similar to Reference Predicate Device

	-Patients who have loose teeth or advanced periodontal disease -Patients who are under 18 years of age -Patients who have Temporomandibular Joint (TMJ) dysfunction	-Patients who have loose teeth or advanced periodontal disease -Patients who are under 18 years of age		
Environment of Use	To be used in the patient's home and in sleep laboratories	To be used in the patient's home and in sleep laboratories	To be used in the patient's home and in sleep laboratories	Same as Primary and Reference Predicate Devices
Design				
Rigid tray pieces	Yes	Yes	Yes	Same as Primary and Reference Predicate Devices
Separate tray pieces	Yes	Yes	Yes	Same as Primary and Reference Predicate Devices
Heat sensitive impression material for fitting to teeth	Yes	Yes	Yes	Same as Primary and Reference Predicate Devices
Provides full occlusal coverage of both arches	Yes	Yes	Yes	Same as Primary and Reference Predicate Devices
Does not encroach on tongue space	Yes	Yes	Yes	Same as Primary and Reference Predicate Devices
Keeps the teeth together and holds the mandible and tongue forward during sleep to open the airway	Yes	Yes	Yes	Same as Primary and Reference Predicate Devices
Fully adjustable	Yes	Yes	Yes	Same as Primary and Reference Predicate Devices
Securely conforms to the patient dentition	Yes	Yes	Yes	Same as Primary and Reference Predicate Devices
Patient Comfort	Yes	Yes	Yes	Same as Primary and Reference Predicate Devices
Materials:				
Trays	Heat sensitive impression material	Heat cure acrylic resin	Heat sensitive impression material	Similar to Primary Predicate Device and Same as Reference Predicate Device

Advancement mechanism	Plastic connectors to position the mandible forward	Stainless Steel Herbst (rod and tube) mechanism to position the mandible forward	Plastic connectors to position the mandible forward	Similar to Primary Predicate Device and Same as Reference Predicate Device
Fabrication Technique	Thermo-molding	Thermo-molding	Thermo-molding	Same as Primary and Reference Predicate Devices
Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile	Same as Primary and Reference Predicate Devices
Biocompatibility (ISO 10993-1)	Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization	Same as Primary and Reference Predicate Devices

G. PERFORMANCE DATA

Prismatik Dentalcraft, Inc. relies on the existing predicated devices for the safety and effectiveness of the Silent Nite® sl for its intended use. Non–clinical (bench performance testing) data was used to support the substantial equivalency.

ASTM D570	Water Sorption
ASTM D790	Water Solubility
ASTM D790	Ultimate Flexural Strength
ASTM D790	Flexural Modulus
ISO 20795-1	Total fracture Work
ASTM D638	Yield Strength
ASTM D412	Tensile Strength
ASTM D638	Elongation at break
ISO 179	Impact Strength

Silent Nite® sl is provided non-sterile and the manufacturing process, material composition, design, and shelf-life is identical to Prismatik's own cleared device, SilentNite® (K972424). No new potential risks were identified and no new concerns were raised for identified risks.

Silent Nite® sl and the primary predicate device, OASYS Hinge Appliance™ (K083209), have the same indications for use and performance characteristics as well as other information on the proposed labeling that support the same intended use.

H. CONCLUSION

The documentation submitted in this premarket notification demonstrates that the Silent Nite® sl is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance, when used as labeled.