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

Re: K211069
Trade/Device Name: EndSnorZ™ Sleep 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
Dated: September 28, 2021
Received: October 1, 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,

For 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)*
K211069

Device Name

EndSnorZ™ Sleep Appliance

Indications for Use *(Describe)*

EndSnorZ™ Sleep Appliance is indicated to reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. EndSnorZ™ Sleep 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.

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 – K211069

Submitter Name:	Prismatik Dentalcraft, Inc.
Submitter Address:	2144 Michelson Drive Irvine, CA 96212
Contact Person:	Herbert Crane Vice President, RA/QA
Telephone:	949.222.3531
Date Prepared:	October 21, 2021
Device Trade Name:	EndSnorZ™ Sleep Appliance
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.
Reference Devices:	#1: K183598, KeyPrint KeySplint Soft, Keystone Industries (Product Codes: MQC, KMY) #2: K203712, The Slide, Biotex, Inc. (Product codes LQZ, LRK)
Indications for Use Statement:	EndSnorZ ™ Sleep Appliance is indicated to reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. EndSnorZ ™ Sleep 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.
Device Description and Summary of Technological Characteristics	The EndSnorZ Sleep Appliance is a mandibular advancement device. It holds the mandible in a protrusive position determined by the trained dentist. The device consists of upper and lower splints (trays), which are additive manufactured using a biocompatible light curable resin, and a connector, made of a biocompatible medical-grade synthetic polymer with injection molding technology. The connectors attach the upper and lower splints to maintain the forward position of the lower jaw. The device is adjustable in 0.5 mm increments. The device is customized to conform to the patient's upper and lower dentition, provided to Prismatik in patient scans. After loading the patient's scan, the splints are designed according to the scan and the clinician's prescription. Prismatik's computer aided design (CAD) software is used for the design phase. The connectors are applied after the splints are manufactured.

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.

Mechanism of Action

The EndSnorZ™ Sleep Appliance is designed so the lower jaw is in an advanced (forward protruding) state during sleep. This forward position improves the flow of air through the patient's pharyngeal space during sleep, repositioning the mandible and thus reducing snoring and mild to moderate OSA.

Device Testing

Laboratory Testing

Testing was performed by Prismatik to:

- validate the design and process for manufacturing the EndSnorZ Sleep Appliance;
- validate the position of the devices on the build platform of the SprintRay 3D printing machine for printing the devices with the Keysplint Soft Resin;
- validate that Prismatik's Wave CAD software accurately designs the sleep appliances and is 21 CFR Part 11 compliant; and
- compare the following mechanical properties of EndSnorZ Sleep Appliance to the Predicate: tensile strength of the connectors and the dimensional retention of connectors when exposed to artificial saliva.

Results of all laboratory testing confirmed substantial equivalence.

Biocompatibility

The following ISO 10993 testing was performed by the manufacturers of the Reference devices' printer resin and the connector polymer to assess the safety and biocompatibility of the resin and synthetic polymer materials.

Part 5 (Cytotoxicity Elution - MEM),
Part 10 (Intracutaneous/Intradermal) Reactivity),
Part 10 (Maximization for Delayed-Type Hypersensitivity)

Prismatik also contracted for GLP Cytotoxicity testing (per ISO 10993, Part 5) of the injection molded connectors.

The test results showed that the materials and the manufactured connectors are safe and biocompatible for the stated intended use.

Animal | Human Testing

No animal or human testing are required for this product type.

Comparison to Predicate and Reference Devices:

The EndSnorZ™ Sleep Appliance as compared to the predicate Silent Nite sl device:

- The intended use is the same.
- The mechanisms of action are the same.
- The materials used to make the device components are similar to the predicate.

Further, the materials and methods for fabricating the splints are the same as the materials and additive manufacturing methods used for Reference #1: The resin is the same KeyPrint KeySplint

Soft resin used for 3D printing the EndSnorZ sleep appliance splints. And, Reference #2 sleep appliance devices are also fabricated with additive manufacturing workflow and methods using a similar light-cured resin.

The following Substantial Equivalence Comparison table includes key similarities and differences of the EndSnorZ Sleep Appliance compared to the Predicate and both Reference devices.

Substantial Equivalence Conclusion

Based on documentation presented in the 510(k), including comparative testing between the subject and Predicate devices, and the presentation of similarities in technological characteristics to the Reference devices, it can be concluded that the differences in the base materials and methods of manufacture do not raise new questions of safety and effectiveness. Thus the EndSnorZ Sleep Appliance is substantially equivalent to the Predicate device.

Substantial Equivalence Comparison Table

Element	New Device	Primary Predicate	Reference Device #1	Reference Device #2	Differences
Device name: 510(k) #:	EndSnorZ Sleep Appliance K211069	Silent Nite® sl K183270	KeyPrint® KeySplint Soft™ K183598	The Slide K203712	N/A
Classification Product Code: Class:	21 CFR 872.5570 LRK II	21 CFR 872.5570 LRK II	21 CFR 872.5570 MQC, KMY II	21 CFR 872.5570 LQZ, LRK II	New device, Predicate and Reference #2: no differences
Submitter:	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	KeyStone Industries	Biotex, Inc.	N/A
Indications for Use:	indicated to reduce snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older. EndSnorZ Sleep 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.	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.	indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and repositioners.	is for use to reduce night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	New device, Predicate, and Reference #2: no differences. Reference #1: may be used during sleep, but not for use to reduce snoring or OSA.
Method of Use:	Single patient user, removable and reusable appliance	Single patient user, removable and reusable appliance	Single patient user, removable and reusable appliance	Single patient user, removable and reusable appliance	None
Rx or OTC	Rx	Rx	Rx	Rx	None
Environment	During sleep at home or in sleep laboratory	During sleep at home or in sleep laboratory	During sleep at home	During sleep at home	As noted
DESIGN:					
Rigid Trays	Upper and lower	Upper and lower	Upper and lower	Upper and lower	None
Adjustable	Yes	Yes	Yes	Yes	None

MATERIALS:					
Splints/Trays	Methacrylate-based light-cured polymer resin used to additively manufacture splints.	Polyurethane or PETG heat-sensitive materials used to manufacture splints	Methacrylate-based light-cured polymer resin used to additively manufacture splints.	Methacrylate-based light-cured polymer resin used to additively manufacture splints	Materials & fabrication method is different compared to predicate but identical to Ref #1 and similar to Ref #2.
Advancement mechanism	Synthetic polymer nylon	Synthetic polymer nylon	N/A	Synthetic polycarbonate	Compared to Predicate same material type but from difference sources, both are manufactured by injection molding methods.
PHYSICAL PROPERTIES					
Connector adjustment range:	20.5mm to 26mm	21mm to 26mm	N/A	N/A	Similar as noted
Maximum adjustment:	5.5mm; increments of 0.5 mm	5.0 mm; increments of 1.0mm	N/A	N/A	Similar as noted
Total achievable mandibular advancement:	Approximately 10mm	Approximately 10mm	N/A	N/A	Similar as noted
STERILITY	Non-sterile	Non-sterile	Non-sterile	Non-sterile	None
BIOCOMPATIBLE	All materials meet requirements of ISO 10993.	All materials meet requirements of ISO 10993.	All materials meet requirements of ISO 10993.	All materials meet requirements of ISO 10993.	None