October 13, 2023

Meris Investment Group
% Janice Farris
Regulatory Affairs Consultant
Prime Path Medtech
811 Lakeview Dr.
Shoreview, Minnesota 55126

Re: K230495
Trade/Device Name: Serena Sleep Night Guard
Regulatory Class: Unclassified
Product Code: MQC, OCO
Dated: September 14, 2023
Received: September 14, 2023

Dear Janice Farris:

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230495

Device Name
Serena Sleep Night Guard

Indications for Use *(Describe)*

The Serena Sleep Night Guard/Occlusal Appliance is a removable medical device that is fitted to the patient's mouth and is intended to protect teeth and restorations against the forces of bruxism and alleviate temporomandibular joint, jaw, and muscle and tension headache pains.

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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Section 5. 510(k) Summary K230495

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter: Serena Sleep

Company Contact Person: Gary Maas, President
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Email: (800) 654-9842
Gary.Maas@serenasleep.com

Submission Correspondent: Janice Farris, Regulatory Affairs Consultant
Address: 811 Lakeview Dr. Shoreview, MN 55126
Phone: (754) 237-8344
Email: jfarris@primepathmedtech.com

Date Prepared: September 12, 2023

Proprietary Name: Serena Sleep Night Guard

Common Name: Mouthguard, Prescription

Product Code: MQC

Subsequent Product Code: OCO

Device Classification: Unclassified

Predicate Device: Panthera Occlusal Appliance (K203596)

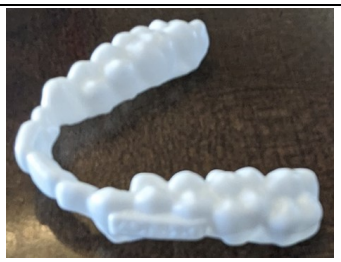
Device Description:

The Serena Sleep Night Guard/Occlusal Appliance is a custom-made intraoral device used for protecting teeth and restorations against the forces of bruxism and alleviating temporomandibular joint, jaw, and muscle and tension headache pains.

Indications for Use:

The Serena Sleep Night Guard/Occlusal Appliance is a removable medical device that is fitted to the patient's mouth and is intended to protect teeth and restorations against the forces of bruxism and alleviate temporomandibular joint, jaw, and muscle and tension headache pains

Comparison to Predicate Device: Night Guard

Specification	***Serena Sleep Night Guard***	**Panthera Occlusal (*Predicate Device*)**	***Comparison Result***
510(k) Number	K230495	K203596	
Device Photo			
Indication for Use	The Serena Sleep Night Guard/Occlusal Appliance is a removable medical device that is fitted to the patient's mouth and is intended to protect teeth and restorations against the forces of bruxism and alleviate temporomandibular joint, jaw, and muscle and tension headache pains.	The Panthera Occlusal Appliance is indicated for protection of teeth and restorations from the forces and damage of parafunctions like bruxism, prevention of noise associated with bruxism, and for alleviation of temporomandibular joint, muscle and tension headache pains associated with temporomandibular disorders	Equivalent
Product Code	MQC, OCO	MQC, OCO	Equivalent
Class	Unclassified	Unclassified	Equivalent
Mechanism of Action	Disocclusion	Disocclusion	Equivalent
Use of Device	Removable intraoral device. Single patient multiple use. Prescription use only.	Removable intraoral device. Single patient multiple use. Prescription use only.	Equivalent
Target Population	Adult patients	Adult patients	Equivalent
Design	Computer-aided design (CAD) from patient dental model or stl file	Computer-aided design (CAD) from patient dental model or stl file	Equivalent
Materials	Polyamide 12 (PA 2200)	Made from polymers (polyamide type 12), metal-free	Equivalent
Manufacturing	Computer-aided manufacturing (CAM)	Computer-aided manufacturing (CAM)	Equivalent
Supplied Sterile/Non-Sterile	Non-sterile	Non-sterile	Equivalent
Biocompatibility: ISO 10993-5	Not performed as the materials are identical to Serena Sleep BMA/EMA (K203606)	Not performed as the materials are identical to Panthera Anti-Snoring Device (K143244)	Equivalent

Non-Clinical Performance Testing (Bench)

The bench testing includes assessment of the physical properties of the Serena Sleep Night Guard/Occlusal Appliance and its ability to achieve its intended use. The submission includes durability testing, manufacturing validation, and testing to the recognized standard ISO 20795-2:2013 Dentistry - Base Polymers - Part 2: Orthodontic Base Polymers (flexural strength, flexural modulus, polishability, water sorption, water solubility, color, freedom from porosity, fracture toughness, max stress intensity factor, and total fracture work).

Clinical Performance Testing

The technological characteristics, indications for use, material, and manufacturing processes are the same or similar to the predicate device and therefore, no Clinical Testing were deemed necessary to demonstrate the safety and effectiveness of the subject device.

Statement of Equivalence

Based on comparison of indications for use, user population, method of manufacturing, non-clinical performance testing, mechanical and technological features, the Serena Sleep Night Guard/Occlusal Appliance has been shown to be substantially equivalent to the legally marketed predicate device. This device does not raise any new safety or effectiveness questions as compared to the predicate device.