March 10, 2021

Meris Investment Group
% Sarah Moss
Regulatory Affairs Consultant
Medavice, Inc
11218 Zest Ct NE
Blaine, Minnesota 55449

Re: K203606
Trade/Device Name: Serena Sleep Block Mandibular Advancement (BMA), Serena Sleep Elastic Mandibular Advancement (EMA)
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: December 10, 2020
Received: December 10, 2020

Dear Sarah Moss:

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 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)*
K203606

Device Name
Serena Sleep Block Mandibular Advancement (BMA)
Serena Sleep Elastic Mandibular Advancement (EMA)

Indications for Use *(Describe)*
The Serena Sleep Appliance is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

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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Section 5. 510(k) Summary - K203606

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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Submission Correspondent:	Sarah Moss, Regulatory Affairs Consultant
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Date Prepared:	December 2020
Proprietary Name:	Serena Sleep Block Mandibular Advancement and Elastic Mandibular Advancement Devices
Common Name:	Device, Anti-snoring
Product Code:	LRK
Device Classification:	Class 2
Predicate Devices:	Block Mandibular Advancement: Prosomnus MicrO2 (Primary Predicate - K133683) Elastic Mandibular Advancement: O2Vent Optima (Reference Device - (K190236)
Device Description:	

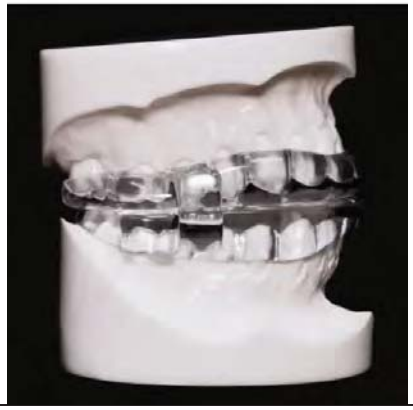
The Serena Sleep Block Mandibular Advancement is an intraoral device that treats snoring and sleep apnea through mandibular repositioning. By positioning the lower jaw forward from its normal location, the patient's pharyngeal space is increased and their ability to exchange air during sleep is improved. This device consists of custom fitted trays which fit over the upper and lower teeth. Based on the physician's prescription, positioning blocks are built into the upper and lower trays The mandibular advancement is achieved through the physician's selection of a specific upper and lower tray that when fitted, sets the optimal mandibular advancement. The separate two-piece construction is desirable for patients that want greater range of motion and lateral movement.

The Elastic Mandibular Advancement model is similar to the Block Mandibular Advancement but has exterior pins that allow for the use of rubber bands rather than the blocks. These bands provide additional treatment options and forces for repositioning the bottom jaw.

Indications for Use:

The Serena Sleep appliance is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

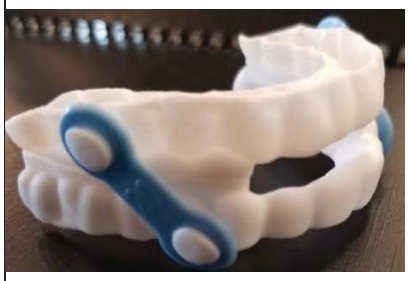
Comparison to Predicate Devices: Block Mandibular Advancement Device

Specification	***Serena Sleep*** ***Block Mandibular Advancement***	**Prosomnus MicrO2** **(*Predicate Device*)**	***Comparison Result***
510(k) Number		K133683	
Device Photo			
Indication for Use	The Serena Sleep Appliance is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The MICRODENTAL, Inc. MicrO2 device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Equivalent
Product Code	LRK	LRK	Equivalent
Regulations	21CFR 872.5570	21CFR 872.5570	Equivalent
Class	2	2	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	People over 18 of age to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults	Equivalent
Device Functionality	Repositions the lower jaw forward.	Repositions the lower jaw forward.	Equivalent
	Acts by increasing the	Acts by increasing the pharyngeal	Equivalent

Specification	***Serena Sleep*** ***Block Mandibular Advancement***	**Prosomnus MicrO2** **(*Predicate Device*)**	***Comparison Result***
	pharyngeal space to improve the patient's ability to exchange air.	space to improve the patient's ability to exchange air.	
	Retains the top and bottom teeth using rigid trays (PA 2200).	Retains the top and bottom teeth using rigid trays (PMMA).	Similar – Different Material
	Upper and lower trays are separate	Upper and lower trays are separate	Equivalent
Device Design and Principle or Operation	Mandibular advancement is achieved through positioning blocks that are built into the upper and lower trays.	Mandibular advancement achieved through twin-mated positioning posts built into the upper and lower trays	Similar – The BMA uses blocks and the MicrO2 uses posts
Means of advancing the mandible	Mandibular advancement achieved via the use of interlocking blocks placed on the trays that are in line with the teeth. The amount of mandibular advancement is based on the location of the "step" relative to the centerline of the block.	Mandibular advancement achieved through twin-mated positioning posts built into the upper and lower trays	Equivalent
Adjustment	Can be adjusted by the clinician.	Can be adjusted by the clinician.	Equivalent
Design	Serena Sleep devices will be designed from digital scans of a patient's dentition. This baseline model of the dentition is provided by the treating dental physician. Using the 3D image of the patient's dentition and the treating physician's indicated mandibular advancement, the patient's custom device is designed by adding blocks. The device is then 3D printed using the material Nylon 12 (PA 2200).	CAD/CAM generated specifically for each prescription and made with a hard PMMA material	Similar – different material

Specification	***Serena Sleep*** ***Block Mandibular Advancement***	**Prosomnus MicrO2** **(*Predicate Device*)**	***Comparison Result***
Supplied Sterile/Non-Sterile	Non-sterile	Non-sterile	Equivalent
Materials: Upper and Lower Trays	Nylon 12 (PA 2200)	Hard PMMA	Similar – different material
Cleaning Instructions	Clean the device after use in water with a soft toothbrush. Rinse, dry, and store in the case provided.	Cleaned daily.	Similar
Biocompatibility : ISO 10993-5	Passed	Not performed as the materials are identical as in the Somnomed MAS RXA (K050592).	Equivalent

Comparison to Predicate Devices: Elastic Mandibular Advancement Device

Specification	***Serena Sleep*** ***Elastic Mandibular Advancement***	**O2Vent Optima** ***(Predicate Device)***	***Comparison Result***
510(k) Number		K190236	
Device Photo			
Indication for Use	The Serena Sleep Appliance is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The O2Vent Optima is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA). The device is indicated for use during sleep to aid in the treatment of these conditions.	Equivalent
Product Code	LRK	LRK	Equivalent
Regulations	21CFR 872.5570	21CFR 872.5570	Equivalent
Class	2	2	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	People over 18 of age to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	People over 18 years of age who snore and/or have sleep apnea.	Equivalent
Device Functionality	Repositions the lower jaw forward.	Repositions the lower jaw forward.	Equivalent
	Acts by increasing the pharyngeal space to improve the patient's ability to exchange air.	Acts by increasing the pharyngeal space to improve the patient's ability to exchange air.	Equivalent

Specification	***Serena Sleep*** ***Elastic Mandibular Advancement***	**O2Vent Optima** ***(Predicate Device)***	***Comparison Result***
	Retains the top and bottom teeth using rigid trays (PA 2200).	Retains the top and bottom teeth using rigid trays (PA 2200).	Equivalent
	Upper and lower trays are separate	Upper and lower trays are separate	Equivalent
Device Design and Principle or Operation	Mandibular advancement using exterior pins that allow for the use of rubber bands rather than the blocks. These bands provide additional treatment options and forces for repositioning the bottom jaw.	The trays have protrusions (lugs) at the side of the upper and lower parts with a connector between the upper and lower parts to stabilize and/or advance the lower jaw.	Equivalent
Means of advancing the mandible	Lower jaw adjusted by attaching connectors of varying lengths	Lower jaw adjusted by attaching connectors of varying lengths	Equivalent
Adjustment	Can be adjusted by the clinician and patient	Can be adjusted by the clinician and patient	Equivalent
Design	Serena Sleep devices will be designed from digital scans of a patient's dentition. This baseline model of the dentition is provided by the treating dental physician. Using the 3D image of the patient's dentition and the treating physician's indicated mandibular advancement, the patient's custom device is designed by adding pins. The device is then 3D printed using the material Nylon 12	Customized for each patient in a dental laboratory located at the manufacturing site based on the dentist prescription Use of computer aided design (CAD) and computer aided manufacturing (CAM) and is made through additive manufacturing using laser sintering of Nylon 12 (PA2200) material. The use of these technologies provides for customization according to the unique characteristics of the patient oral anatomy based on the prescription provided by the clinician	Equivalent
Adjustment Accessory	Replacement/Re-supply connectors (13-21 mm)	Replacement/re-supply connectors (13-21 mm)	Equivalent
Supplied Sterile/Non-Sterile	Non-sterile	Non-sterile	Equivalent
Materials: Upper and Lower Trays	Nylon 12 (PA2200)	Nylon 12 (PA2200)	Equivalent

Specification	***Serena Sleep*** ***Elastic Mandibular Advancement***	**O2Vent Optima** ***(Predicate Device)***	***Comparison Result***
Materials: Straps	100% thermoplastic Polyurethane/cured elastomer	100% thermoplastic Polyurethane/cured elastomer	Equivalent
Cleaning Instructions	Clean the device after use in water with a soft toothbrush. Rinse, dry, and store in the case provided.	Clean the device daily in lukewarm water with a soft toothbrush. Rinse, dry, and store in the case provided.	Equivalent
Biocompatibility : ISO 10993-5	Passed	Passed	Equivalent

Performance Testing (Bench)

Testing was conducted to compare the Serena Sleep Block Mandibular Advancement device and Elastic Mandibular Advancement device to mechanical forces found through a literature search of maximum jaw strengths. Compression, Shear, and Bruxism forces were tested, as well as a product durability test for one year of use. The bench testing proved that they devices were able to withstand forces greater than expected jaw forces during nighttime jaw clenching and bruxing.

A key design advantage of the Serena Sleep products are its ability to customize the amount of mandibular advancement for each patient. This feature allows the doctor the ability to find a setting that is right for each patient.

Therefore, the performance of the Serena Sleep device were shown to be at least equivalent to the predicate devices.

Clinical Testing

No Clinical Testing was required for this product.

Statement of Equivalence

Block Mandibular Advancement

As summarized above, the main differences between the subject (Serena Sleep BMA) and predicate (Prosomnus MicrO2) devices are:

- Predicate device does not use PA2200 in the additive manufacturing process
- Predicate device uses positioning pins instead of positioning blocks

Based on comparison of indications for use, user population, performance testing, mechanical and technological features, the Block Mandibular Advancement device 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.

Elastic Mandibular Advancement

As summarized above, there are no functional differences between the subject (Elastic Mandibular Advancement Device) and predicate (O_2Vent Optima) devices.
Based on comparison of indications for use, user population, performance testing, mechanical and technological features, the Elastic Mandibular Advancement device 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.