May 3, 2024

EMA Sleep Incorporated
℅ Cheryl Fisher
Principal Consultant
FisherMed Consulting LLC
820 Civic Center Drive
Santa Clara, California 95050

Re: K232735
Trade/Device Name: EMA 3D
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, LQZ
Dated: February 5, 2024
Received: February 5, 2024

Dear Cheryl Fisher:

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., RAC, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232735

Device Name

EMA 3D (EMA 3D)

Indications for Use *(Describe)*

The EMA 3D 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.

510(k) Summary

EMA 3D

K232735

1. Submission Sponsor

EMA Sleep Incorporated

27005 Masters Parkway

Spicewood, TX

78669

United States

Contact: Joseph Frantz

Title: President

2. Submission Correspondent

FisherMed Consulting, LLC

820 Civic Center Drive

Santa Clara, CA 95050

Office Phone: (408) 410-5920

Contact: Cheryl Fisher

Title: Principal Consultant, RA/QA

3. Date Prepared

4/30/24

4. Device Identification

Trade/Proprietary Name:	EMA 3D
Common/Usual Name:	Intraoral Devices for Snoring and /or Obstructive Sleep Apnea
Classification Name:	Intraoral Devices for Snoring and /or Obstructive Sleep Apnea
Regulation Number:	872.5570

Product Code: LRK, Device, Anti Snoring- Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.

LQZ, Device, Jaw Repositioning- Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea

Device Class: Class II

Classification Panel: Dental

5. Legally Marketed Predicate Device(s)

Primary Predicate
K203606 Serena Sleep Elastic Mandibular Advancement

Secondary Predicate
K971794 Elastic Mandibular Advancement

Reference Devices
K183598 KeySplint Soft
K203000 KeySplint Hard

6. Indication for Use Statement

The EMA 3D 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.

7. Device Description

The EMA 3D device is a simple hardware device. It is an oral appliance and will be manufactured by a dental laboratory to and on the order of a dentist, physician or licensed practitioner. Each appliance is customized for patients.

The EMA 3D device is intra-oral device used for treating snoring and mild to moderate Obstructive Sleep Apnea (OSA). It has a patented button hook design with variable elastic band for optimum titration with bitewing if needed. The device consists of two custom fitted trays which fit over the upper and lower dentition of a patient. The trays are standard biocompatible trays that do not reposition teeth. Each tray holds the teeth in their present location not allowing tooth movement. The devices function as mandibular repositioners, which act to increase the patient's pharyngeal space by reducing obstructions of the airway during sleep and improve their ability to exchange air.

There are four button hooks utilized on the EMA 3D device (two hooks per tray, two trays top and bottom. The hooks must be placed at a distance of 21mm apart from the top tray hook to the bottom tray hook center to center. Though there is no requirement except the 21mm apart. The opitimum location for hook placement between the top and bottom trays is on the upper bicuspid and the lower first molar.

It is important to note the hooks are made of the same material as the trays and are integrated as a part of the fabrication process.

Button hooks and bite blocks for the EMA 3D utilize standard dimensions.

These button hooks serve as fastening anchors for Elastic Straps that come in four different color coded strengths:

1. White-Soft
2. Yellow-Medium
3. Blue-Firm and
4. Clear- Extra Firm

These straps also come in 9 different lengths such that the Dental Professional can ensure the patient specific correct amount of mandibular advancement the lengths are as follows:

1. 21mm
2. 20mm
3. 19mm
4. 18mm
5. 17mm
6. 16mm
7. 15mm
8. 14mm
9. 13mm

8. Substantial Equivalence Discussion

The following table compares the EMA 3D to the Secondary Predicate and reference device(s) and Primary Predicate with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the Secondary Predicate device.

Table 5A – Comparison of Characteristics

9. Feature	**EMA 3D**	**Secondary Predicate** **Elastic Mandibular Advancement**	**Reference Device 1** **KeySplint Soft**	**Reference Device 2** **KeySplint Hard**	**Primary Predicate** **Serena Sleep Elastic Mandibular Advancement**	**Comparison**
510 (k) Number	K232735	K971794	K183598	K203000	K203606	Same method
Manufacturer	EMA Sleep Incorporated	Donald Frantz, DDS (Patent Holder of EMA system) Meyerson	Keystone Industries	Keystone Industries	Serena Sleep Solutions	NA
		Primary Device Similarities to support Substantial Equivalence				
Classification #	872-5570	872-5570	Unclassified	Unclassified	872-5570	Same
Product Code	Primary LRK	Primary LRK	Primary MQC Secondary KMY	Primary MQC Secondary KMY/EBI	Primary LRK	Same

Intended Use population	Adults, Transitional Adolescent (A&B),	Adults, Transitional Adolescent (A&B), and Adolescent	Not defined Current Market Usage: Adults, Transitional Adolescent (A&B), and Adolescent	Not defined Current Market usage: Adults, Transitional Adolescent (A&B), and Adolescent	Adults and Transitional Adolescent (A&B)	Same as Primary Predicate Similar to Secondary Predicate . Reference devices 1 and 2 are dental resins the EMA 3D is made of therefore the intended population includes adults and transitional Adolescent (A&B) but is also used in Adolecents for the use of retainers made of the resins
Indications for use	The EMA 3D is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring	Treatment of nasal respiratory dysfunction of obstructive sleep apnea and snoring in those patients where	The KeyPrint® KeySplint Soft™ device is indicated for the fabrication of orthodontic and dental appliances	The KeyPrint" KeySplint HardTM device is indicated for the fabrication of orthodontic and dental appliances such as mouthguards,	The Serena Sleep Appliance is a removable medical device that is fitted in the patient’s mouth	Same as Primary Predicate Serena Sleep EMA Similar to Secondary

	and mild to moderate obstructive sleep apnea (OSA) in adults.	repositioning of the mandible can increase the patients air space.	such as mouthguards, nightguards, splints and repositioners	nightguards, splints, repositioners and retainers.	and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Predicate device the original EMA Reference devices 1 and 2 are the resins used by the EMA Sleep Inc. to make the trays used in the EMA 3D therefore the indications for use are not the same
Target Population	Adults diagnosed with mild to moderate sleep apnea	Adults diagnosed with mild to moderate sleep apnea	Patients diagnosed with the need for dental appliances for multiple conditions	Patients diagnosed with a need for dental appliances for multiple conditions	Adults diagnosed with mild to moderate sleep apnea obstructive sleep apnea (OSA) in adults	Same as Primary Predicate and Secondary Predicate
Single or Family submission	Single	Single	Single	Single	Family	Same as Secondary Predicate and reference devices 1 and 2.

						Member of the Primary Predicate family.
Mode of Action	These devices function as a mandibular repositioner, which acts to increase the patient's pharyngeal space, by reducing obstructions of the airway and improving their ability to exchange air during sleep.	These devices function as a mandibular repositioner, which acts to increase the patient's pharyngeal space, by reducing obstructions of the airway and improving their ability to exchange air during sleep.	Not Applicable This is a dental resin the mode of action is determined by the type of device the material is fabricated to be	Not Applicable This is a dental resin the mode of action is determined by the type of device the material is fabricated to be	Mandibular advancement achieved through twin-mated positioning posts build into the upper and lower trays	Same mode of action for both the PrimaryPredicate Device and Secondary Predicate Reference devices 1 and 2 are the dental resins used to make the EMA 3D trays
Functionality	Consists of an upper and lower appliance that are 2 separate appliances that work in conjunction with each other – via an embedded button hook and variable	Consists of an upper and lower appliance that are 2 separate appliances that work in conjunction with each other – via a an embedded button hook and variable size and	Not Applicable This is the dental resin used to fabricate the trays for the EMA 3D device	Not Applicable This is the dental resin used to fabricate the trays for the EMA 3D device	Consists of an upper and lower appliance that are 2 separate appliances that work in conjunction with each other –via a an embedded button hook and variable size and strength elastic bands that allows the	Functionality is the same for the EMA 3D, its Primary Predicate specifically the Serena Sleep Solutions Elastic Family member of the Primary predicate and its

	size and strength elastic bands that allows the dental professional to properly adjust the devices to patient dentition and physiological need ultimately reducing pharyngeal obstruction through mandibular advancement	strength elastic bands that allows the dental professional to properly adjust the devices to patient dentition and physiological need ultimately reducing pharyngeal obstruction through mandibular advancement			dental professional to properly adjust the devices to patient dentition and physiological need ultimately reducing pharyngeal obstruction through mandibular advancement	Secondary Predicate .
Tray Material	**Keystone** KeySplint Hard FDA (K203000) KeySplint Soft FDA (K183593)	EMA PETG	Same This is the dental resin used to fabricate the trays for the EMA 3D device	Same This is the dental resin used to fabricate the trays for the EMA 3D device	**Serena Sleep Solutions** Nylon 12	Similar in strength and biocompatibility and performance aspects of both the PrimaryPredicate device and Secondary Predicate different material The EMA 3D utilizes tray

						material of the fabricated dental resins identified as Reference devices 1 and 2
Material Connecting Mechanism	Thermoplastic Elastomer (TPE) and colorant for White, Yellow and Blue Elastic Straps No colorant utilized Clear Elastic straps	Thermoplastic Elastomer (TPE) and colorant for White, Yellow and Blue Elastic Straps No colorant utilized for Clear Elastic straps	Not Applicable This is the dental resin used to fabricate the trays for the EMA 3D device	Not Applicable This is the dental resin used to fabricate the trays for the EMA 3D device	Thermoplastic Elastomer (TPE) and colorant for White, Yellow and Blue Elastic Straps No colorant utilized for Clear Elastic straps	Same
Connecting Mechanism	Button hook system with Elastic Straps	Button hook system with Elastic Straps	Not Applicable This is the dental resin used to fabricate the trays for the EMA 3D device	Not Applicable This is the dental resin used to fabricate the trays for the EMA 3D device	Button hook system with Elastic Straps	Same
Range and Precision of adjustment	Front to back +/- 1mm	Front to back +/- 1mm	Not Applicable This is the dental resin used to fabricate the	Not Applicable This is the dental resin used to fabricate the	Front to back +/- 1mm	Same

			trays for the EMA 3D device	trays for the EMA 3D device		
Maximum Mandibular Advancement	14 mm	14 mm	Not Applicable This is the dental resin used to fabricate the trays for the EMA 3D device	Not Applicable This is the dental resin used to fabricate the trays for the EMA 3D device	14mm	Same as Primary Predicate Device and Secondary Predicate
Mode of Care	Adjustable by Dentist or Physician during the duration of use	Adjustable by Dentist or Physician during the duration of use	Not Applicable This is the dental resin used to fabricate the trays for the EMA 3D device	Not Applicable This is the dental resin used to fabricate the trays for the EMA 3D device	Adjustable by Dentist or Physician during the duration of use	Same
Usage	Removable and Reusable by the same patient. Night Time Usage Only	Removable and Reusable by the same patient. Night Time Usage Only	In fabricated form Removable and Reusable by the same patient. Night Time Usage Only	In fabricated form Removable and Reusable by the same patient. Night Time Usage Only	Removable and Reusable by the same patient. Night Time Usage Only	Same
Sterility	Non-sterile device cleaned between	Non-sterile device cleaned between	Not Applicable	Not Applicable	Non-sterile device cleaned between uses	Non-sterile device cleaned

	uses by the patient following instructions provided by its manufacturer	uses by the patient following instructions provided by its manufacturer	This is the dental resin used to fabricate the trays for the EMA 3D device EMA 3D device is Non-sterile device cleaned between uses by the patient following the instructions for use provided by the fabricated device manufacturer	This is the dental resin used to fabricate the trays for the EMA 3D device EMA 3D device is Non-sterile device cleaned between uses by the patient following the instructions for use provided by the fabricated device manufacturer	by the patient following instructions provided by its manufacturer	between uses by the patient following instructions provided by its manufacturer
Biocompatible	Yes	Yes	Yes	Yes	Yes	Same
OTC or Rx	Rx	Rx	Rx	Rx	Rx	Same
		Device Technological Differences Difference				
Tray Materials	EMA-3D- KeySplint Hard FDA (K203000) KeySplint Soft FDA (K183593)	EMA Custom-PETG	This is the dental resin used to fabricate the trays for the EMA 3D device	This is the dental resin used to fabricate the trays for the EMA 3D device	Serena Sleep Solutions Nylon 12	**PETG/TPU, EVA** PETG/TPE, Nylon, Keystone KeySplint materials have different physical

						properties. Each material utilized has a long and successful history of use in the orthodontic and oral appliance devices. They are biocompatible, durable and have sufficient strength to perform the intended functions of the device in accordance with each patients' specific clinical needs. Therefore, there are no additional risks incurred by the patient

Fabrication	3D Printed	Thermoformed	3D Printed	3D Printed	Laser Sintering	The different fabrications utilized are all commonly used in the dental industry for dental and orthodontic appliances they are all capable of creating product that meets specified requirements with no additional risks to the patient.

The EMA 3D device shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the Primary Predicate and Secondary Predicate device(s). The EMA 3D is similar in design and function to the Primary and Secondary Predicate devices for the modes of operation and use.

Performance Testing Summary

The EMA Sleep Incorporated utilized risk management techniques identified in ISO 14971 Application of Risk Management to medical devices.

Standard Physical Properties testing was completed on the EMA 3D device components using accepted standards including:

Strength Flexural Testing:

#	**Standard**
1	ISO 20795-2 Ultimate Flexural Strength, Flexural Modulus, Sorption, Solubility, Free Monomer Extraction, as applied by Keystone industries in the KeySplint Soft Material
2	ASTM, D790-17, Standard Test Methods for Flexure Properties of Unreinforced Plastics and Electrical Insulating Materials, 2016 as applied by the Keystone Industries in KeySplint Hard Material

Additionally, **Biocompatibility** testing was completed on the individual components of this device in accordance with the recommendations of ISO, 10993-1, Biological Evaluation of Medical Devices, 06/30/2010, for this type of device.

Internal verification and validation testing confirms that product specifications are met which are equivalent in design and technological characteristics as the Primary and Secondary Predicate devices

All testing was considered successful and met identified acceptance criteria. Results demonstrate performance commensurate with the indications for use, in the intended use environment and supports the claims of substantial equivalence to the Primary and Secondary Predicate devices.

Comparison Discussion:

The differences between the EMA 3D and its predicate and reference devices are not significant and do not affect the substantial equivalence of the device. Most of the differences documented between the EMA 3D and its predicate and reference device(s), primarily the predicate devices are related to fabrication method and materials which have similar strengths and biological and technical characteristics that satisfy the intended use of the devices cleared for similar indications for use. The reference devices 1 and 2 that are resins are the same resins used to fabricate the EMA 3D device.

The EMA 3D device has similar intended uses and technological characteristics as compared to the predicate device and reference device(s) and therefore are substantially equivalent to the to the predicate and reference device(s).

10. Non-Clinical Performance Data

As part of demonstrating the substantial equivalence of the EMA 3D to the Secondary Predicate/reference devices that are subject to this 510(k) submission, EMA Sleep Incorporated utilized Elastic straps that have been previously cleared by the FDA under K97194 and utilized FDA cleared materials under K203000 and K183598 that have undergone the following performance testing:

Strength and Flexural testing:

#	**Standard**
1	ISO 20795-2 Ultimate Flexural Strength, Flexural Modulus, Sorption, Solubility, Free Monomer Extraction
2	ASTM, D790-17, Standard Test Methods for Flexure Properties of Unreinforced Plastics and Electrical Insulating Materials, 2016

The EMA 3D passed all the testing in accordance with internal requirements, applied national standards, and applied international standards shown below to support substantial equivalence of the subject device:
Biocompatibility - The biological safety of the components of the EMA 3D were evaluated in accordance with ISO 10993-1 and guidance document entitled Use of International Standard ISO-10993-1,"Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing within a Risk Management Process". Under this, for the stated indications for use, each component of the device's biological safety was evaluated for in vitro cytotoxicity, skin sensitization, and irritation, and mutagenicity and chemical characterization.

- Biocompatibility testing per ISO 10993-1 Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing within a Risk Management Process: Assessed
- Biocompatibility testing per ISO 10993-5 Cytotoxicity: Passed
- Biocompatibility testing per ISO 10993-10 Test for irritation and Skin Sensitization Passed

Risk Analysis - Formal Risk Assessment of the EMA 3D was performed in accordance with ISO 14971. With respect to perceivable conditions in which the device would be subjected to a worst-case environmental or human error scenario, EMA Sleep Incorporated believes the outcomes of these risks

are considered acceptable within the context of ISO 14971, and that all potential risks have been mitigated to the lowest form.

11. **Performance Testing Summary**

As part of demonstrating the substantial equivalence of the EMA 3D and in showing substantial equivalence to the Secondary Predicate devices that are subject to this 510(k) submission, EMA Sleep Incorporated completed a number of tests. The EMA 3D met all the requirements for overall design, biocompatibility, and performance testing confirming that the output meets the design inputs and specifications. The EMA 3D passed all required testing stated above as shown by the acceptable results obtained.

The EMA 3D complies with the applicable voluntary standards for biocompatibility per materials used. The device passed all the testing in accordance with national and international standards relative to their intended use.

12. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the differences between the EMA 3D and the Primary Predicate or Secondary Predicate device do not raise any different questions regarding its safety and effectiveness. The performance testing provided demonstrates that the subject device(s) are substantially equivalent to the Primary and Secondary Predicate device and reference devices. The EMA Sleep Incorporated , EMA 3D as designed and manufactured, are determined to be substantially equivalent to the Primary and Secondary Predicate devices and reference device(s).