February 2, 2024

Myohealth Technologies, LLC
% Colette Cozean, Ph.D.
Regulatory Consultant
The EyeDeas Company
21581 Midcrest Dr
Lake Forest, California 92630

Re: K230548
Trade/Device Name: Myoaligner Appliance
Regulatory Class: Unclassified
Product Code: MQC, OCO
Dated: January 18, 2024
Received: January 19, 2024

Dear Colette Cozean, Ph.D.:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230548

Device Name
Myoaligner Appliance

Indications for Use *(Describe)*
For protection against teeth grinding, bruxism, and jaw clenching; protection of restorations from injury due to bruxism or clenching; relief of bruxism related headaches, migraines and pain; short-term relief from muscle spasm due to occlusal interference; prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscles; and temporary treatment of temporal mandibular disorder (TMD) along with the relief of associated headaches and pains in adults 18 years of age or older.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

Applicant:	Myohealth Technologies, INC 13765 NW Cornell Rd. Suite 150 Portland, Oregon 97229 763-363-3336 drm@myoaligner.com
Contact Person:	Colette Cozean, PhD 21581 Midcrest Drive Lake Forest, CA 92630 (949) 855-2885 colettecozean@gmail.com
Date Prepared	February 2, 2024
Proprietary Name	Myoaligner Appliance
Common Name	Mouthguard, Prescription
Classification Name	Unclassified
Product Code	MQC
Subsequent Product Code	OCO
Primary Predicate Device	SmartGuard Night Guard, Original, Night Guard Original and Elite (K123161)
Predicate Devices	Somnobrux Splints including Michigan, ComnBrux B, Gelb and Tanner (K102909), Serena Sleep Night Guard (K230495)
Reference Devices	NTI-TSS (K010876) and The POD (K182820) for comparison in performance testing, PMMA Blocks from Huge Dental Material Co. (K201683)

Description: The Myoaligner appliance is a customized, removable dental device which is designed to overlay the existing dentition without the need for any alterations done to the receiving dentition. The appliance is a plural piece intra-oral removable appliance, which is designed and delivered to the patients by a licensed practitioner such as a dentist (Rx only). The dentist can prescribe a device that fits over the 4-6 front teeth, back teeth on both sides of the dental arch or all of the teeth in the dental arch both on the upper or lower jaw. The appliance is held in place by mechanical retention. The Myoaligner appliance can be worn on either the top or bottom teeth or both. It is intended for use in adults 18 years of age and older.

Indications for Use: For protection against teeth grinding, bruxism, and jaw clenching; protection of restorations from injury due to bruxism or clenching; relief of bruxism related headaches, migraines and pain; short-term relief from muscle spasm due to occlusal interference; prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscles; and temporary treatment of temporal mandibular disorder (TMD) along with the relief of associated headaches and pains in adults 18 years of age or older.

Technological Characteristics, Components and Materials, Manufacturing Methods: The appliance is digitally designed based on the specific dental records (stone models or digital 3D scans of the patient's maxillary and mandibular arches), which are provided by the dentist. After being digitally designed to the dentists' specifications, the oral appliance is fabricated by an FDA registered milling center utilizing the process of milling a polymethyl methacrylate (PMMA) block. These precision CAD CAM milling machines are currently used for manufacturing orthotics in the dental industry. A predicate, Serena Sleep Night Guard, is milled in this fashion.

DEVICE ILLUSTRATIONS AND DRAWINGS

Figure 1 below provides an overall view of the Myoaligner device and how the device is intended to overlay the dentition. As displayed, the Myoaligner is form-fit to the dentition such that the device is capable of functioning even without use of adhesives. Myoaligner is a plural piece device that is fabricated to overlay one section of the dental arch or several sections of the dental arch depending on the specific prescription that was submitted by the dental provider. In the images below, the Myoaligner is illustrated in 3 individual piece sections (2 posterior and 1 anterior section) to overlay the entire lower dental arch. The device is designed based on the specific prescription that was submitted by the dental provider and at times may only cover sections of the dental arch or the entire arch.

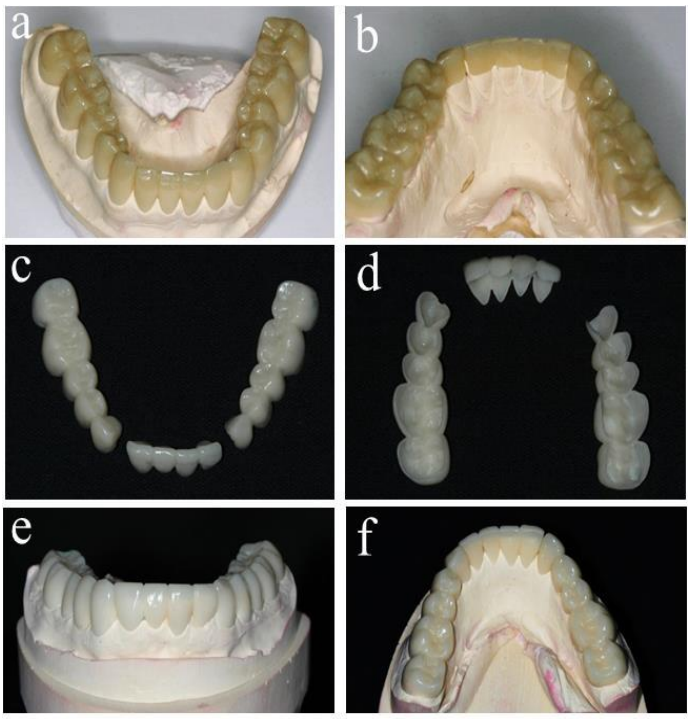


Figure 1: Images of the Myoaligner device and exemplary fit to the dentition. a) Anterior /superior view showing the precise fit on a dental model of the Myoaligner over the lower dentition b) Posterior/superior view of the Myoaligner on the dentition model, c) Superior/exterior view of the Myoaligner device which has been fabricated to form-fit the dentition, d) Bottom/interior view of the Myoaligner device, e and f) Anterior and posterior/superior view of the Myoaligner device positioned on the model of the dentition; respectively.

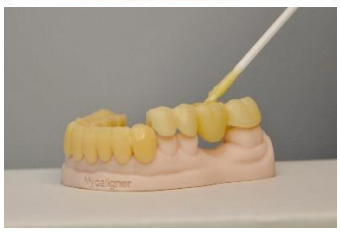
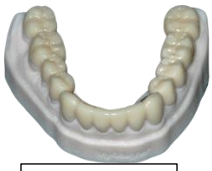


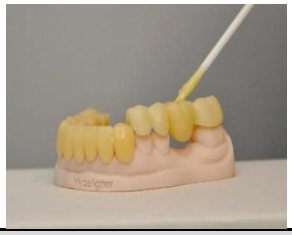
Image of device in 3 components



Full Arch

Mechanism of Action: Removable dental appliance therapy is a treatment modality in which the patient wears a removeable appliance that overlays the teeth or dental arches. It prevents the occlusal inteferences from coming into occlusion, which relaxes the jaw muscles and helps to reduce jaw clinching and grinding and reduces associated symptoms such as headaches, migraines, pain and muscle spasming. The same mechanism of action is used with mouthguards and the predicate devices.

Substantial Equivalence:

	Subject Device	Primary Predicate Device	Predicate Device	Predicate Device
Trade Name	Myoaligner	SmartGuard Night Guard, Original, Night Guard Original and Elite	Somnoburx Splints including Michigan, ComnBrux B, Gelb and Tanner	Serena Sleep Night Guard
Owner	Myohealth Technologies	SmartGuard	Somnomed	Serena Sleep
510(k) Number		K123161	K102909	K230495
				
Intended Use				
Indication for Use		OTC: > Protection against bruxism or nighttime teeth grinding > Intended to reduce damage to the teeth and reduce noise associated with bruxing and/or grinding.		
	Rx:	Rx:	Rx:	Rx:
	> Protection of teeth grinding, bruxism and jaw clenching	> Protection of teeth grinding, bruxism and jaw clenching	>Protection of teeth and restoration from the forces of Bruxism	>Protect teeth and restorations against the forces of bruxism and alleviate temporomandibular joint, jaw and muscle and tension headache pains
	>Protection of restoration from injury due to bruxism or clenching	>Protection of restoration from injury due to bruxism or clenching		
	>Relief of bruxism related to headaches and pains	>Relief of bruxism related to headaches and pains		
	> Short-term pain relief from muscle spasm due to occlusal interference; for the prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle	> Short-term pain relief from muscle spasm due to occlusal interference; for the prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle		
	>Temporary treatment of Temporal Mandibular Disorder (TMD) along with the relief of associated headaches and pains	>Temporary treatment of Temporal Mandibular Disorder (TMD) along with the relief of associated headaches and pains		

Class	Unclassified	Unclassified	Unclassified	Unclassified
Product Code	MQC, OCO	MQC, OBR	MQC	MQC, OCO
Intended for single patient multiuse	Yes	Yes	Yes	Yes
Design				
Customized fit for each patient	Yes, in the lab	Yes, at home boil-n-bite	Yes, in the lab	Yes, in the lab
Trays	Upper and Lower Tray (full and partial)	Upper Tray Only (6-8 teeth), bottom teeth contacts the bottom of the substrate	Michigan and ComnBrux fit on the maxillary arch; Gelb and Tanner fit the mandibular arch; Gelb fits the posterior teeth	Custom-made intraoral device that is fitted to the patient's mouth via computer aided design and manufacturing
Adhesives	None	None	None	None
Cleaned and inspected daily by patient	Yes	Yes	Yes	Yes
Composition				
Material	PMMA	Elvax	PMMA	Polyamide 12 (PA 2200)
Mechanism				
Mechanism of Action	Prevent teeth grinding and relax muscles by placing appliance between the teeth	Prevent teeth grinding and relax muscles by placing appliance between the teeth	Prevent teeth grinding and relax muscles by placing appliance between the teeth	Disocclusion

Clinical and Non-Clinical Data: A biocompatibility and physical properties assessment was completed based on the material composition of the predicates, which concluded that the subject device was substantially equivalent to the predicate devices. The Company uses the PMMA material from Huge Dental Material Co with no changes to the chemical composition, no surface coating or treatments and no additional dyes or colorants. The tint is selected from a selection of tints provided by Huge Dental. A risk assessment has also been conducted with the subject device, which concluded there are no additional risks as compared to the predicate device(s).

Performance Testing: The PMMA material conforms to ISO 10477. Performance testing confirmed the Myoaligner anterior segment retention is equivalent to reference device NTI-TSS, the Myoaligner posterior segments are equivalent to the predicate Gelb Appliance. Performance testing was also done to show the effects of repeated use (insertion and removal) and articulating paper to show interdigitation and canine guidance.

Manufacturing: The Myoaligner is manufactured in the same manner as the predicate device, Serena Sleep Night Guard. The Myoaligner is manufactured from PMMA blocks manufactured by Huge Dental Material Co (K201683). Each PMMA material manufacturer has met the ISO 10477 guidance and has their own submission on file with the FDA including composition, physical properties and tints.

Differences:

1. Myoaligner offers full or partial upper and lower trays. SmartGuard fits the front 6-8 teeth and NTI (reference device for mechanical testing) fits the front 4-6 teeth as does one Myoaligner version. Somnobrux manufactures 4 versions, 2 upper trays and 2 lower trays. Michigan and Tanner splints cover

the whole arch while the Gelb splint covers the posterior teeth only. One of these predicates cover each of the different Myoaligner designs. The POD (reference device for mechanical testing) also covers all teeth.

2. The Myoaligner can be prescribed for use during the day or night for 8-10 hours per day, while the predicates are prescribed at night only except for The POD which is prescribed for nighttime use up to 12 hours and the NTI-TSS, which can be prescribed for day or night use.

Summary: Based on the intended use, technical characteristics, biocompatibility assessment, manufacturing process, labeling and other data provided in this submission, the Myoaligner appliance demonstrates substantial equivalence to the predicate devices and reference devices in both safety and efficacy.