March 2, 2026

Myofunctional Research Co.
℅ Colette Cozean
Quality and Regulatory Affairs Manager
dba The EyeDeas Company
21581 Midcrest Dr.
Lake Forest, California 92630

Re: K252531
Trade/Device Name: Myosa (S1H, S1, S2, S3, S1M, S2M); Myosa for Snorers (S1, S1M, S2)
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 26, 2026
Received: February 26, 2026

Dear Colette Cozean:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252531 ?
Please provide the device trade name(s).	?

Myosa (S1H, S1, S2, S3, S1M, S2M);
Myosa for Snorers (S1, S1M, S2)

Please provide your Indications for Use below. ?

Rx: The Myosa (S1H, S1, S1M, S2, S2M and S3) appliances are intended to treat snoring and/or mild to moderate obstructive sleep apnea in adults at least 18 years old.

OTC: The Myosa for Snorers (S1, S1M and S2) are intended to treat snoring in adults at least 18 years old.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C) ?

510(k) #: K252531

510(k) Summary

Prepared on: 2026-02-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Myofunctional Research Co.
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Correspondent Contact	Dr. Colette Cozean
Correspondent Contact Email	colettecozean@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Myosa (S1H, S1, S2, S3, S1M, S2M); Myosa for Snorers (S1, S1M, S2)
Common Name	Mouthguard
Classification Name	Device, Anti-Snoring
Regulation Number	872.5570
Product Code(s)	LRK, LQZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K132506, K191618	SleepTight Mouthpiece (STM)	LRK
K111680, K182312	Zyppah	LRK
K231663	AVEOtsd	LRK

Device Description Summary

21 CFR 807.92(a)(4)

The Myosa and Myosa for Snorers appliances open the airway, control over-breathing through the mouth and posture the jaw and tongue correctly during sleep. The mechanisms of use are mandibular advancement, repositioning the tongue and training nasal breathing. Models S1H, S1, S2, and S3 are pre-fabricated oral devices (mouthguards); Models S1M and S2M are moldable boil and bite devices.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Rx: The Myosa (S1H, S1, S1M, S2, S2M and S3) appliances are intended to treat snoring and/or mild to moderate obstructive sleep apnea in adults at least 18 years old.

OTC: The Myosa for Snorers (S1, S1M and S2) are intended to treat snoring in adults at least 18 years old.

Indications for Use Comparison

21 CFR 807.92(a)(5)

All Rx devices (Myosa, SleepTight and Zyppah) are intended to treat snoring and/or mild to moderat obstructive sleep apnea in adults (18 years and older). All OTC devices (Myosa for Snorers, Sleep Tight, Zyppah and AVEOStd) are intended to treat or reduce snoring in adults (18 years and older).

Technological Comparison

21 CFR 807.92(a)(6)

AVEOStd and Myosa/Myosa for Snorers (S1H, S1, S2, S3) are made of silicone, while the boil and bite appliances are made of EVA over a hard core of polypropylene for Zyppah and for Myosa/Myosa for Snorers. All Myosa appliances, SleepTight and Zyppah Rx slightly move the jaw forward. All devices position the tongue. All Myosa appliances guide the tongue forward and upward while the tongue elevator trains the tongue to stay in this position. SleepTight passively retains the tongue. Zyppah actively retains the tongue with a silicone strap while AVEOstd uses suction to retain the tongue.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

N/A