November 6, 2025

Aiomega, LLC
Raghavendra Ghuge
President and CEO
3187 Paluxy Drive
Tyler, Texas 75701

Re: K252525
Trade/Device Name: AIO Breathe
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: August 6, 2025
Received: November 6, 2025

Dear Raghavendra Ghuge:

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.

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
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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.	K252525

Please provide the device trade name(s).

AIO Breathe

Please provide your Indications for Use below.

The AIO Breathe is intended to reduce snoring and to treat mild and moderate obstructive sleep apnea in children 6-17 years of age who are diagnosed with snoring and/or mild or moderate obstructive sleep apnea.

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) Summary

Sponsor Information:
AIOMEGA, LLC
3187 Paluxy Drive
Tyler, TX 75701-8303

Contact Person	Dr. Raghavendra Ghuge Founder, CEO raghu.ghuge@aiomd.com (903) 316-1269
Date of Summary	November 5, 2025

Device Name and Classification

Proprietary Name:	AIO Breathe
Common or Usual Name:	Device, Jaw Repositioning; Device, Anti-Snoring
Classification Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea. (21 CFR § 872.5570)
Classification Product Code:	LQZ, LRK
Predicate Device:	AIO BREATHE (K233754)

Device Description
AIO Breathe consists of two separate intraoral trays (upper, lower) that are customized to fit over all the teeth. The device is manufactured at AIOMEGA facilities using additive manufacturing with Stereolithography (SLA) 3D printing technology that builds the device from biocompatible resins. The customized trays are fabricated based on intraoral scans provided by the dentist and the dentist's prescription.

AIO Breathe features right and left protrusive flanges on the buccal sides of the upper tray. These flanges engage with corresponding right and left vertical flanges featured on the buccal sides of the lower tray. This engagement repositions the jaw to reflect the dentist’s prescribed anterior mandibular advancement.

Additionally, mandibular plateaus, as prescribed by the dentist, featured on the right, and left occlusal cranial surfaces of lower tray, guide the mandible downward, thus opening the anterior airway. The plateaus and flanges allow vertical opening of the jaw (jaw is not fixed in a single position) and work together to maintain advancement in open and closed mouth positions. This design feature allows more room and creates traction for the tongue to migrate forward. The resulting mechanical protrusion increases the patient’s pharyngeal space, improving their ability to exchange air, thereby reducing the tendency to snore and alleviating signs of obstructive sleep apnea.

Operating Principle
AIO Breathe is a traction-based mandibular repositioning device that features two separate trays worn on

the maxilla and mandible. The device is custom fabricated to the patient's unique dentition and is intended to maintain an open airway during sleep by advancing the mandible and tongue.

Because patients in the intended age range (6–17 years) may experience changes in dentition, jaw alignment, and overall craniofacial development, it is the dentist's responsibility to periodically assess fit and function. If growth or dental changes alter the fit or effectiveness of the device, the AIO Breathe shall not be adjusted or modified. Instead, the dentist is required to obtain new dental impressions or digital scans and order a replacement device to maintain proper fit, function, and therapeutic advancement.

The device permits anterior, vertical, and lateral jaw movements, and is designed to maintain an open airway intended to increase air exchange:

- by anterior advancement of the mandible and tongue.
- throughout opening and closing movements of the mouth.
- throughout lateral movements of the mandible.

Indications for Use
The AIO Breathe is intended to reduce snoring and to treat mild and moderate obstructive sleep apnea in children 6-17 years of age who are diagnosed with snoring and/or mild or moderate obstructive sleep apnea.

Biocompatibility
Biocompatibility testing was completed on the materials to be used in accordance with ISO 7405 and ISO 10993. The manufacturing process and materials of the subject device are identical to the predicate device AIO Breathe in K233754.

Predicate and Reference Comparison Summary

Feature	Subject Device AIO Breathe	Predicate (K233754) AIO Breathe	Reference (K234089) DNA Appliance	Comparison Summary
Regulation	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	Identical
Product Code	LRK, LQZ	LRK, LQZ	LRK, LQZ	Identical
Intended Use	Treatment of snoring and mild to moderate OSA in children ages 6–17	Treatment of snoring and mild to moderate OSA in adults	Treatment of snoring and OSA in children ages 6–17	Intended use aligns with predicate and reference; only population differs
Prescription Use	Yes	Yes	Yes	Identical
Design	Two custom-fit trays with mandibular advancement	Two custom-fit trays with mandibular advancement	Similar (with mechanical adjustment)	Technologically equivalent
Materials	Formlabs Dental LT Clear V2	Formlabs Dental LT Clear V2	Orthodontic acrylics	Biocompatible and functionally equivalent materials
Operation Principle	Mandibular advancement to maintain open airway	Mandibular advancement to maintain open airway	Mandibular advancement to maintain open airway	Identical
Manufacturing	CAD/CAM 3D printed	CAD/CAM 3D printed	Cast	Equivalent performance
Sterility	Non-sterile	Non-sterile	Non-sterile	Identical
Use Environment	Dentist-fitted, home use	Dentist-fitted, home use	Dentist-fitted, home use	Identical

Substantial Equivalence Discussion
The AIO Breathe Pediatric device is substantially equivalent to the predicate AIO Breathe (K233754) with the DNA Appliance (K234089) serving as a reference device for the pediatric indication.

Intended Use:
The only difference from the predicate device is the target population (children ages 6–17). The fundamental intended use—to reduce or alleviate snoring and treat mild to moderate obstructive sleep apnea by advancing the mandible—is unchanged.

Technological Characteristics:
The subject device shares identical materials, design features, manufacturing process, and operating principles with the predicate device. These similarities ensure equivalent safety and performance.

Reference Device Support:
The DNA Appliance (K234089) provides FDA precedent for the safe and effective use of mandibular advancement devices in children ages 6–17, supporting that the change in patient population does not raise new questions of safety or effectiveness.

Risk Mitigation and Labeling:
Pediatric-specific risks (tooth movement, occlusal changes, or growth-related fit issues) are addressed through:

- Custom fabrication and professional oversight
- Periodic dental follow-up
- Non-adjustable design and labeling to replace if fit changes

Clinical Data:
Clinical performance data are not required, as the subject device is technologically identical to the predicate and supported by a cleared reference device for the same pediatric indication. Non-clinical testing (biocompatibility, mechanical integrity, and risk analysis) adequately demonstrates safety and performance.

Non-Clinical Performance Testing:
Non-clinical performance testing in accordance with recommendations in Special Controls Guidance Document: *Intraoral Devices for Snoring and /or Obstructive Sleep Apnea – Class II Special Controls Guidance Document for Industry and FDA (*November 2002).

Conclusion

The AIO Breathe for pediatric is substantially equivalent to the predicate AIO Breathe (K233754).

The difference in patient population does not introduce new safety or effectiveness concerns and is supported by the reference device DNA Appliance (K234089), which demonstrates established FDA acceptance of similar technology in pediatric patients.