February 23, 2024

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

Re: K233754
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: LQZ, LRK
Dated: November 22, 2023
Received: November 22, 2023

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.

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
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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)*
K233754

Device Name
AIO Breathe

Indications for Use *(Describe)*
Intended to reduce or alleviate snoring, mild to moderate Obstructive Sleep Apnea (OSA) while sleeping 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K233754

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	February 14, 2024

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.
Classification:	Class II
Regulation Number:	21 CFR 872.5570
Classification Product Code:	LQZ, LRK
Predicate Device:	Slow Wave DS8 (K191320)

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 acts to increase 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 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

AIO Breathe is intended to reduce or alleviate snoring, mild to moderate Obstructive Sleep Apnea (OSA) while sleeping in adults.

Biocompatibility

Biocompatibility testing was completed on the materials to be used in accordance with ISO 7405 and ISO 10993.

Comparison of Technology

AIO Breathe applies the same technology as the predicate device, Slow Wave DS8 in terms of the following:

- It has essentially the same intended use and is indicated for the same patient population.
- It has similar technological characteristics to the predicate device.
- It has the same material composition as the predicate device.

Clinical Test Summary

No clinical studies were conducted on AIO Breathe.

Conclusion

Based on the similarity in technology and indications for use to the predicate device, we believe that AIO Breathe is substantially equivalent to Slow Wave DS8 (K191320).