July 12, 2023

Achaemenid LLC
% Joseph Azary
Regulatory Consultant
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K230532
Trade/Device Name: RADx Intraoral Appliance for Snoring and Sleep Apnea
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: June 15, 2023
Received: June 22, 2023

Dear Joseph Azary:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
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)*

K230532

Device Name

RADx Intraoral Appliance for Snoring and Sleep Apnea

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.

510(k) Summary
ACHAEMENID RADx INTRAORAL APPLIANCE FOR SNORING & SLEEP APNEA

1. SUBMITTER/510(K) HOLDER

Achaemenid LLC
2318 Main Street
Stratford, CT 06615

Contact Name: Joseph Azary (Aztech Regulatory & Quality LLC)
Email: jazary@erols.com
Telephone: (203) 242-6670

Date Prepared: February 23, 2023

2. DEVICE NAME

Proprietary Name:	RADx Intraoral Appliance for Snoring and Sleep Apnea
Common/Usual Name:	Intraoral Devices for Snoring and Obstructive Sleep Apnea
Classification Name:	Intraoral Devices for Snoring and Obstructive Sleep Apnea
Classification Regulation:	21 CFR 872.5570
Classification Product code:	LQZ
Subsequent Product Code:	LRK
Classification:	Class 2
Medical Specialty (Panel):	Dental

3. PREDICATE DEVICES

- Primary Predicate Device – Slow Wave DS8, 510(k) K191320
- Reference Predicate Device – Panthera Anti-Snoring Device, 510(k) K143244

4. DEVICE DESCRIPTION

The RADx White Night and RADx White Night-p Intraoral Appliance for Snoring and Mild to Moderate Sleep Apnea are removable intraoral devices used for treating snoring and mild to moderate obstructive sleep apnea. It consists of two custom fabricated adjustable rods that fit separately over the upper and lower teeth. The device functions as a mandibular repositioner, maintaining the lower jaw in a forward position during sleep. This mechanical protrusion acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep. The device is a prescription device customized for each patient and has an adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device. The device can be adjusted only by the user and / or the dentist in increments of 0.5 mm.

The custom oral appliance is checked for proper and comfortable fit as well as the appropriate initial progressive arm attachment. The dentist will provide the patient with subsequent progressive arms from 1.0 mm up to 5.0mm in 0.5mm increments.

There are 9 different arms each identified with a number for each side of the jaw. The arms are also identified as either "L" for left or "R" for right.

Variants / Configurations

There are two variants of the device.

The RADx White Night has removable progressive arms with the female housing active as the receptacle for the arms.

The RADx White Night-p was designed with the upper housing and arm as one piece. In this version, the fixed upper tray-arm combination are the progressive parts of the entire apparatus.

5. INTENDED USE

Intended to reduce or alleviate snoring, mild to moderate Obstructive Sleep Apnea (OSA) while sleeping in adults.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject device has the same intended use, materials and operating principles as the predicate devices. Additionally, the differences in technological characteristics do not raise new questions of safety or effectiveness. Therefore, based on the substantial equivalence evaluation, the company concludes that the subject device is equivalent to the predicate devices.

7. PERFORMANCE TESTING

The following standards were either used as a reference and/or for testing of the subject device:

- Cytotoxicity Testing per ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity.
- Intracutaneous Irritation Testing per ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.
- Sensitization Testing per ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.
- Systemic Toxicity Testing per ISO 10993-11 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.
- Pyrogen Testing per United States Pharmacopeia 43, Formulary 38, General Chapter <151>, Pyrogen Test.
- Genotoxicity Testing per ISO 10993-3 Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- Acute Systemic Toxicity per United States Pharmacopeia 35, Biological Reactivity Tests, In Vivo
- Implantation per United States Pharmacopeia 35, Biological Reactivity Tests, In Vivo

Summary of Testing

Standard	Description of Test	Results
ISO 10993-5 (2009) Cytotoxicity BioMed Clear and dental LT Clear V2 Resins	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity ISO Elution Method	Non-Cytotoxic
ISO 10993-5 (2009) Cytotoxicity BioMed Clear and dental LT Clear V2 Resins	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity MTT Cytotoxicity Test	No cytotoxic potential
ISO 10993-10 (2010) Sensitization BioMed Clear and dental LT Clear V2 Resins	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization ISO Guinea Pig Maximization Sensitization Study	Non-sensitizer
ISO 10993-10 (2010) Irritation BioMed Clear and dental LT Clear V2 Resins	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization USP Intracutaneous Study in Rabbits	Non-Irritant
ISO 10993-10 (2010) Irritation BioMed Clear and dental LT Clear V2 Resins	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization ISO Oral Mucosal Irritation Study in Hamsters 14 day	Non-Irritant
USP 88 Acute Systemic Toxicity BioMed Clear and dental LT Clear V2 Resins	United States Pharmacopeia 35, Biological Reactivity Tests, In Vivo Acute Systemic Toxicity	No evidence of systemic toxicity
USP 88 Implantation BioMed Clear and dental LT Clear V2 Resins	United States Pharmacopeia 35, Biological Reactivity Tests, In Vivo Modified USP Muscle Implantation Study in Rabbits – 7 day	Macroscopic reaction was not significant as compared to the negative control article.
ISO 10993-11 (2017) Systemic Toxicity BioMed Clear and dental LT Clear V2 Resins	Biological Evaluation of Medical Devices – Part 11: Test for systemic toxicity	Non-Toxic

USP 43, National Formulary 38, General Chapter <151> (2020) Pyrogen Test BioMed Clear and dental LT Clear V2 Resins	Pyrogen Test	Absence of Pyrogens
ISO 10993-3 (2003) Genotoxicity BioMed Clear and dental LT Clear V2 Resins	Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Non-Mutagenic

8. SAFETY AND EFFICACY

Biocompatibility: A biocompatibility assessment of the device was performed. The purpose of the biocompatibility assessment was to ensure that biocompatibility had been established for the device. The device is biocompatible, based on the identical use of materials of construction of the predicate devices.

Clinical Testing: Human clinical studies were not deemed necessary to evaluate the safety or effectiveness of the subject device. The subject device uses similar designs as the predicate devices, uses identical materials, had same indications for use, and equivalent technological characteristics.

Risks: As with the predicate devices, the subject device can have risks for dental or soft tissue soreness, TMJ dysfunction, obstruction to oral breathing, dental movement or changes in dental occlusion. The Instructions for Use include warnings, precautions and contraindications to address such risks.

The device is manufactured using the same equipment and same materials as the predicate devices.

9. CONCLUSION

Information presented supports substantial equivalence of the RADx Intraoral Appliance for Snoring and Sleep Apnea to the predicate devices based on similarities in intended use, design, principles of operation, material composition and performance specifications.

Achaemenid LLC believes that based on the indications for use, technological characteristics, and comparison to predicate devices the RADx Intraoral Appliance for Snoring and Sleep has been shown to be substantially equivalent to the predicate and is safe and effective for its intended use.