August 25, 2026

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

Re: K254304
Trade/Device Name: iNOS intraoral biosensor
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: PLC, DQA, OUG, LQZ, LRK
Dated: July 29, 2026
Received: July 29, 2026

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 (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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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
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OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K254304

Device Name
iNOS intraoral biosensor

Indications for Use *(Describe)*
The iNOS intraoral biosensor is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Additionally, the fully embedded oximeter sensor measures, displays, stores and transmits functional oxygen saturation of the arterial hemoglobin (SpO2). It is intended for continuous data collection during sleep. It can be used in sleep labs, long term care, hospitals and home use.

The device is intended to be applied in the oral cavity. The device is intended for use under non-motion conditions in well perfused areas. The device is single patient, reusable.

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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K254304

510(k) Summary
iNOS INTRAORAL BIOSENSOR

1. SUBMITTER/510(K) HOLDER

Achaemenid, LLC
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Contact Name: Joseph Azary (Aztech Regulatory & Quality LLC)
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Telephone: (203) 242-6670

Date: August 21, 2026

2. DEVICE NAME

Proprietary Name:	iNOS Intraoral Biosensor
Common/Usual Name:	Intraoral device for snoring and/or obstructive sleep apnea with patient monitoring
Classification Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Classification Regulation:	21 CFR 872.5570
Classification Product code:	PLC
Classification:	Class 2
Medical Specialty (Panel):	Division of Dental and ENT devices
Secondary Product Codes:	DQA, LQZ, LRK, OUG

3. PREDICATE DEVICES

- Primary Predicate Device – Achaemenid – RADx Intraoral Appliance – K230532
- Secondary Predicate Device – ProSomnus RPMO2 OSA Device – K252765

4. DEVICE DESCRIPTION

The iNOS Intraoral Biosensor is a medical grade oximeter hermetically sealed inside an upper or lower arch oral appliance.

Achaemenid obtained 510(k) clearance for an intraoral appliance used for snoring and obstructive sleep apnea. The company used that design concept and materials to create an intraoral biosensor to be used as a pulse oximeter.

The iNOS Intraoral Biosensor is placed in the patient's mouth.

The device is used for oximetry reading during sleep from the oral soft tissue structure, when worn by an individual. The iNOS Intraoral Biosensor tracks blood oxygen saturation or SpO2 as a way to track sleep quality.

The device is paired with a smart electronic device that has the iNOS app. The data is transmitted via Bluetooth to the smart electronic device so that the data can be reviewed.

Principles of Operation

The device measures red, green and infrared light through perfused tissue to detect fluctuating signals caused by arterial pulses. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin from the color difference by measuring the ratio of absorbed red, green and infrared light as volume fluctuates with each pulse.

Battery

The battery is a 3.7V lithium ion battery with a 30mAh capacity. A charged battery can be used for 8 hours. The battery and sensor are hermetically sealed within the oral appliance and cannot be removed or replaced.

Physical Aspects

The iNOS Intraoral Biosensor is approximately 40mm x 10mm x 2mm in size to allow comfortable usage within the mouth.

Electrical / Software Aspects

The iNOS Intraoral Biosensor includes an internal batter powered sensor to measure pulse oximetry. The device is low power and complies with applicable electrical safety requirements including IEC 60601-1, IEC 60601-1-2, IEC 60601-1-2 and ISO 80601-2-61.

The battery can be recharged.

The sensor has firmware installed and an internal antenna. The sensor communicates with the app that is installed on a smart electronic device.

The app on the smart electronic device receives and decrypts the transmitted information to allow display.

Wireless Features

The Bluetooth transmissions are encrypted using ICS Certification AES128 encryption.

The Bluetooth operates in the 2.4 GHz ISM band (2400 to 2483.5 MHz). The Bluetooth utilizes Adaptive Frequency Hopping (AFH) as an inherent coexistence mechanism.

Functionality with Smartphones and Tablets

The application gets sent to the customers after ordering a device. The app is installed on a smart electronic device and then gets paired with the iNOS Intraoral Biosensor.

Description of the App

The App is used to display pulse oximetry measurements and it is up the Healthcare Professional to review, analyze and determine how to use that data.

Built In Safety Features

The iNOS Intraoral Biosensor is a low power device that meets applicable electrical safety standards.

The device also meets the ingress protection requirements outlined in IPx2.

The materials used for the device are identical to the materials used in the RADx Intraoral Appliance cleared under K230532. These materials have been tested to biocompatibility test requirements.

Biocompatibility

Biocompatibility was addressed in accordance with FDA's guidance document "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" and ISO 7405 "Dentistry – Evaluation of Biocompatibility of Medical Devices used in Dentistry".

The materials in contact with the patient for the subject device are identical to the materials and processes (e.g. housing material & fabrication, post-print processing / cleaning agents, mold release agents and housing cure / post-cure) used in the RADx Intraoral Appliance cleared under K230532. The encapsulation process does not introduce biological hazards when compared to the primary and secondary predicate devices. Therefore, the biocompatibility of the subject device is supported by the biocompatibility information for the primary predicate device.

Accuracy

The accuracy of the pulse oximeter was evaluated at University of California San Francisco, where it was found to provide accurate results when tested with 25 patients with different genders, age groups and racial backgrounds.

Software and Cybersecurity

Software documentation was provided in accordance with the FDA guidance "Content of Premarket Submissions for Device Software Functions".

The iNOS device contains firmware that acquires multi-channel PPG and 6-axis IMU raw sensor data continuously during sleep monitoring sessions. Sensor data is transmitted to the companion Android application via encrypted BLE in real time. The firmware stores sensor data to an on-board flash memory during BLE disconnection events, provide up to 30 minutes of local buffering.

The iNOS Android Application is the companion software for the device. It provides BLE based connection, real time physiological signal display, signal processing algorithms (i.e. SpO2) and local data storage and export. The software falls under Class A.

Software Verification and Validation was conducted with passing results.

The submission includes cybersecurity documentation in accordance with FDA guidance "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions" including cybersecurity testing (vulnerability assessment and penetration testing). The device meets the requirements of section 524(b) of the Food Drug & Cosmetic (FD&C) Act.

5. INDICATIONS FOR USE

The iNOS intraoral biosensor is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Additionally, the fully embedded oximeter sensor measures, displays, stores and transmits functional oxygen saturation of the arterial hemoglobin (SpO2).It is intended for continuous data collection during sleep. It can be used in sleep labs, long term care, hospitals and home use.

The device is intended to be applied in the oral cavity. The device is intended for use under non-motion conditions in well perfused areas. The device is single patient, reusable.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The similarities between the devices are as follows:

- All devices are indicated to reduce snoring and mild to moderate obstructive sleep apnea.
- The subject device and secondary predicate also include functionality to measure oxygen saturation.
- All devices are used in the oral cavity
- All devices are custom maxillary and mandibular arches composed of medical grade copolyester and adhesive.
- The subject device and secondary predicate collect data continuously during sleep.
- The subject device and secondary predicate both have SpO2 accuracy of 70-100%.
- The subject device and secondary predicate use Rechargeable Lithium Ion Batteries and meet IEC electrical safety standards.
- All of the devices are non-sterile
- The subject device and secondary predicate have wireless capabilities using Bluetooth Low Energy (BLE) with a range of 10 meters.
- All devices are single patient use, reusable.

The main differences are identified as:

- The primary predicate does not have a sensor to measure SpO2 and is not battery powered.
- The subject device was testing to IP22 for ingress protection whereas the secondary predicate was tested to IP68 for device and IP22 for charger.
- The subject device has a rechargeable battery that lasts approximately 8 hours

which is appropriate as the patient wears it while sleeping, whereas the secondary predicate has battery life of 4+ hours of continuous recording per session.

The main differences are not deemed significant based on the testing to electrical safety standards including IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 and ISO 80601-2-61, as well as the oximetry accuracy study.

7. PERFORMANCE TESTING

The iNOS Intraoral Biosensor was subjected to a variety of testing including:

- Biocompatibility Evaluation per ISO 10993-1
- Electrical Safety Testing
- Performance of Pulse Oximeters per ISO 80601-2-61
- Software Verification and Validation
- Pulse Oximetry Accuracy

Test Name	***Test Description and acceptance criteria***	***Remarks - Conclusions***
Electromagnetic Disturbance (EMC) Testing	Testing for compliance to acceptance criteria in the EMC standard IEC 60601-1-2:2014 / AMD1:2021. The testing included mains terminal disturbance voltage, electromagnetic radiation disturbance, harmonic current emissions, voltage fluctuations, Flicker, and Immunity.	PASS All testing included as part of the EMC testing including immunity, voltage fluctuations, electromagnetic disturbance, harmonic current emissions all passed.
Electrical Safety	Testing for compliance to IEC 60601-1:2005/AMD2:2020 Testing included ingress, determination of accessible parts, rough surfaces/sharp corners, excessive temperature, humidity pretreatment, dielectric strength, push, impact, drop test, and mold stress relief.	PASS The testing concluded that the device complied with applicable portions of the IEC 60601-1 standard.

Test Name	*Test Description and acceptance criteria*	*Remarks - Conclusions*
Electrical Safety - Home Healthcare Environment	Testing for compliance to IEC 60601-1-11:2015/AMD1:2020	PASS The testing concluded that the device complied with applicable portions of the IEC 60601-1-11 standard.
Basic Safety and Essential Performance of Pulse Oximeter Equipment	Testing for compliance to ISO 80601-2-61:2017 and IEC 60529 Testing included ingress, settings and data storage after interruptions, faults and shock and vibration.	PASS The testing concluded that the device complied with applicable portions of the ISO 80601-2-61 and IEC 60529. Ref: 092-721010024-000
Wireless Coexisternce Testing	Testing to ensure the device will function properly in an environment with other electronic devices in use.	PASS The iNOS intraoral biosensor met the recommended test level as defined in ANSI C63.27
Cytotoxicity	Testing for compliance to ISO 10993-5	PASS The device was non-cytotoxic. Meets requirements.
Skin Irritation in Rabbits	Testing for compliance to ISO 10993-10	PASS Non-Irritant. Meets requirements.
ISO Closed Patch Sensitization in Guinea Pigs	Testing for compliance to ISO 10993-10	PASS Non-sensitizer and met requirements.
Acute Systemic Toxicity	Testing for compliance to USP 88 for Acute Systemic Toxicity	PASS No evidence of systemic toxicity and compliant with USP 88.
Implantation	Testing for compliance to USP 88 for Implantation.	PASS Macroscopic reaction was not significant as compared to the negative control article.
Systemic Toxicity	Testing for compliance to ISO 10993-11	PASS The device was not toxic and was compliant to ISO 10993-11
Genotoxicity	Testing for compliance to ISO 10993-3	PASS The device was non-mutagenic and was compliant to ISO 10993-3.

Test Name	*Test Description and acceptance criteria*	*Remarks - Conclusions*
Pulse Oximeter Testing Report	The testing included 25 patients.	PASS The testing was conducted using co-oximetry reference.

8. CONCLUSION

Information presented supports substantial equivalence of the subject device to the predicate devices based on similarities.

The company believes that based on the indications for use, technological characteristics and comparison to predicate devices the subject device has been shown to be substantially equivalent to the predicate and the minor differences do not impact safety and effectiveness.