March 13, 2026

Iasis Technologies
% Vaibhav Rajal
Official Correspondent for Iasis Technologies Corporation
Mdi Consultants, Inc.
55 Northen Blvd., Suite 200
Great Neck, New York 11021

Re: K252923
Trade/Device Name: IASIS i2 Relaxation Neurofeedback System
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback device
Regulatory Class: Class II
Product Code: SEN, HCC
Dated: February 12, 2026
Received: February 13, 2026

Dear Vaibhav Rajal:

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,

PAMELA D. SCOTT -S

Pamela D. Scott, MS
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine 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)*
K252923

Device Name
IASIS i2 RELAXATION NEUROFEEDBACK SYSTEM

Indications for Use *(Describe)*
IASIS i2 Relaxation Neurofeedback System is a neurofeedback device intended for relaxation and stress reduction through the use of EEG biofeedback.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

March 13, 2026

1. **Applicant Details**

Applicants Name:	IASIS Technologies Corporation
Address:	38975 Sky Canyon, Suite 105| Murrieta, CA 92563
Contact Person:	Lawrence Wedekind, CEO
Cell Phone:	832-236-2265
E-mail	lwedekind@iasistech.com

2. **Official Correspondent**

Contact Person:	Mr. Vaibhav Rajal
Company Name	mdi Consultants, Inc.
Address	55 Northern Blvd. Suite 200, Great Neck, NY 11021
Phone	201-887-3180
Email	Vaibhav@mdiconsultants.com

3. **Alternate Official Correspondent**

Contact Person:	Ms. Susan D Goldstein-Falk
Company Name:	mdi Consultants, Inc.
Address:	55 Northern Blvd. Suite 200, Great Neck, NY 11021
Phone:	949-282-9524
Email:	sgoldstein@mdiconsultants.com

4. **Indications for use of the device**

IASIS i2 Relaxation Neurofeedback System is a neurofeedback device intended for relaxation and stress reduction through the use of EEG biofeedback.

5. Device Information

- Trade Name: IASIS i2 RELAXATION NEUROFEEDBACK SYSTEM
- Regulation Number: 21 CFR 882.5050
- Regulation Name: Biofeedback device
- Regulatory Class: Class II
- Product Code: SEN, HCC
- Review Panel: Neurology

6. Legally Marketed Predicate Devices

a. Primary Predicate Device:

- 510(K) Number: K945826
- Trade/Device Name: J&J I-330 SERIES PHYSIOLOGICAL MONITORING & BIOFEEDBACK INSTUMENT AND USE SOFTWARE APPLICATIONS
- Regulation Number: 21 CFR 882.5050
- Regulation Name: Biofeedback device
- Regulatory Class: Class II
- Product Code: HCC
- Review Panel: Neurology

b. Secondary Predicate Device:

- 510(K) Number: K990538
- Trade/Device Name: The BrainMaster 2E MODULE AND SOFTWARE BIOFEEDBACK DEVICE
- Regulation Number: 21 CFR 882.5050
- Regulation Name: Biofeedback device
- Regulatory Class: Class II
- Product Code: HCC, GWQ
- Review Panel: Neurology

7. Device Description

IASIS i2 Relaxation Neurofeedback System is a medical device system prescribed for providing relaxation and stress reduction biofeedback treatment. It consists of a multi-channel EEG recording device and the software running on a Windows laptop.

The IASIS i2 Relaxation Neurofeedback System includes an EEG recording device encased in a plastic enclosure. It is connected to the laptop with a standard USB-A to USB-C cable capable of drawing at least 3 Amps of power. The device is powered by the laptop through the USB cable. The device has 9 standard, electrically safe DIN 42802 single-pin input connectors. Pre-existing EEG lead wires with integrated Ag/AgCl EEG electrodes made by Rhythmlink International, LLC (K061148), and Elefix V Paste for EEG & EMG made by Nihon Kohden Corporation (K191975) are connected to the input connectors of the device. The device does not have any user controls; it is turned on and off by the IASIS i2 Relaxation Neurofeedback System software through the USB connection. The device has a single indicator of operation – a cyclic pattern illumination is applied to the translucent plastic logo and a plastic rim around the bottom of the device when it is turned on.

The device has at least 2 input raw EEG channels with 24-bit A/D resolution. This enables it to deliver more than 12 significant bits of EEG signals without the need for heavy analog filters, which significantly distort the raw EEG signals. It samples all input channels at least at a 250 Hz sampling rate.

The device provides an industry-standard level of electrical safety against up to 5000V of electric shock from the power line. It also provides ESD protection of input channels for up to 15,000V.

The IASIS i2 Relaxation Neurofeedback System software is a desktop application installed and run on a laptop under Windows 10 or newer. The software operates in two modes: Cloud or Local. When it operates in Cloud mode, clinicians utilize

the IASIS Cloud Portal – a web application running on the cloud server providing comprehensive patient management functions. To run a new biofeedback session, the clinician logs into the portal, selects a patient from the patient directory, and launches a new session. The web application launches the IASIS i2 Relaxation Neurofeedback System software on the laptop to start a new session.

The IASIS i2 Relaxation Neurofeedback System is designed to be Internet-independent in the case of absence or poor Internet connection by operating in the local mode. If the clinician switches to the local mode, the software uses the local data storage, which automatically synchronizes with the Cloud storage when an Internet connection becomes available.

When a new biofeedback session is started, the clinician uses an intuitive graphical user interface to set all parameters needed for the session: selecting EEG topical sites where the EEG electrodes will be placed and selecting the type of biofeedback protocol. It also prompts the clinician to measure the impedance of all assigned EEG electrodes, checks raw EEG signals, and begins a new biofeedback session.

The electrode impedance is measured every time the electrode placement is conducted or changed. The duration of standard neurofeedback protocols is short, which does not lead to noticeable deterioration of the electric contact between electrodes and skin after proper placement and impedance measurement. Therefore, continuous real-time electrode impedance measurement is not required.

During the session, the IASIS i2 Relaxation Neurofeedback System software displays raw EEG signals to control the quality of input data, their real-time spectral images, and all standard brainwave amplitudes. It also displays the current threshold of the target EEG band according to the selected training protocol. When the selected EEG band hits the threshold level, the system may provide visual or auditory feedback.

Once the training session is completed, the software shows a session preview with the target EEG brainwaves recorded during the session. The clinician saves the results of the session in the local data storage, and the system automatically

synchronizes the data to the cloud storage when an Internet connection is available.

The IASIS i2 Relaxation Neurofeedback System provides maximum security for the recorded information, including available patient health information, by storing all data in the local or cloud storage in an encrypted format and transmitting the information over the Internet using a secure data transmission protocol.

8. Substantial Equivalence Discussion:

Parameter Item Description*	**Proposed Subject Device**
510K Number	K252923
Device Name	IASIS i2 Relaxation Neurofeedback System
Indication For Use Statement	IASIS i2 Relaxation Neurofeedback System is a neurofeedback device intended for relaxation and stress reduction through the use of EEG biofeedback.
Intended Use	Utilize biofeedback technology based on visual and/or auditory signals to help patients regulate and voluntarily control their physiological parameters
Classification	device, biofeedback Class II
FDA Product Code	HCC
FDA Regulation	882.5050
Operation Principle	The device provides neurofeedback training using standard EEG protocols for stress reduction and relaxation by enhancing certain brainwave bands and inhibiting others.
Intended User	Healthcare professional
Biofeedback assessment mode	A combination of a 2-channel isolated physiological signal recorder and Windows-based physiological monitoring software capturing raw EEG signals, analysis of brainwaves, and generating visual/audio biofeedback signals based on preset protocols.
Supported Devices	IASIS i2 5-channel Isolated Physiological Signal Recorder (2 channels used)
Number of EEG Channels	2
Sampling Rate	250 Hz

Digital Notch Filter	50/60 Hz
Analog bandpass filter	Analog anti-alias filters on input channels. On-chip (delta-sigma ADC) decimation filters provide additional anti-aliasing filters
Digital bandpass filter	0.5 – 40 Hz
Electric Isolation	5 kV
Power source	From USB through 5 kV isolation
Device operation indication	24 LED
Full-scale Input range	+/- 187.5 mV
Input channel noise level	2.1 uVrms
ADC Resolution	24-bit
Effective number of bits	12
Computer interface	USB 2.0
Dimensions	170 x 140 x 30 mm
Input connector	9 single-pin DIN 42802
Input Impedance	100 MOhm
Application software	Running on a local Windows PC
Connection to the Internet	Device operates in either Internet or local mode using the cloud-based or local database respectively. Cloud and local DB are synchronized when Internet connection is present. When Internet is not available, it forces using local data storage.
Data encryption	HTTPS (AES-256 encryption, TLS protocol)
Electrode impedance measurement	Performed at the beginning of each training session upon electrode placement

DISCUSSION OF SIMILARITIES AND DIFFERENCES:

Similarities:

1. **Indications for Use**: The proposed subject device shares a similar indication for use as the predicate device. Both are neurofeedback devices intended for

relaxation and stress reduction through the use of EEG biofeedback. The proposed subject device shares a similar indication for use and technology as the secondary predicate device.

2. **Operational Principle and Biofeedback Mode**: The proposed subject device, predicate device and secondary predicate operate on the same basic principle—capturing EEG signals and analyzing brainwaves for neurofeedback training to promote relaxation and stress management.
3. **Technical Parameters**: Key technical specifications such as sampling rate, digital notch filter, digital bandpass filter, electric isolation, and input impedance are substantially equivalent across all three devices.
4. **Input Impedance**: The input impedance of 100 MΩ is substantially equivalent across the subject device and the predicate device, supporting substantial equivalence in signal acquisition performance.

Differences:

1. **Power Source**: The power source used by the subject device differs from that of the predicate device. Despite this, the power configuration does not introduce new risks or compromise the device's effectiveness.
2. **Number of LEDs**: The subject device uses a different number of LEDs than the predicate device. This difference does not affect the device's safety or performance.
3. **Input Channel Noise Level**: The subject device exhibits an input channel noise level that is slightly lower than the predicate devices. This variation does not introduce new safety concerns or reduce effectiveness.
4. **Device Dimensions**: The physical dimensions of the subject device differ from those of the predicate device. However, the size variation does not raise any safety or effectiveness concerns.
5. **Internet Connectivity**: The subject device includes a feature for internet connectivity. As demonstrated in the accompanying software and cybersecurity documentation, this feature introduces no additional safety or risk concerns.
6. **Data Encryption**: The subject device incorporates data encryption, which enhances data security. This feature has been validated as safe and effective, as supported by the submitted software and cybersecurity documentation.

9. Summary of Nonclinical Test Conclusion

The following Non-clinical tests were conducted to verify that the proposed device met all design specifications and to demonstrate the safety & effectiveness of the subject device. The test results demonstrated that the proposed device meets the acceptance criteria for the following standards and the requirements stated in the guidance for industry and FDA staff; surgical mask-premarket notification:

- IEC 60601-1-2:2014+A1:2020: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC TS 60601-4-2 Edition 1.0 2024-03 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.
- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- California Proposition 65 Compliance
- CISPR 11:2015+A1:2016+A2:2019 - Limits and methods of measurement of radio disturbance, Characteristics of industrial, scientific and medical radio frequency equipment
- IEC 61000-4-2:2008 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 2: Electrostatic discharge immunity test
- IEC 61000-4-3:2010 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 3: Radiated, radiofrequency, electromagnetic field immunity test
- IEC 61000-4-39:2017- Electromagnetic Compatibility (EMC) -- Part 4-39: Testing And Measurement Techniques - Radiated Fields In Close Proximity - Immunity Test
- IEC 61000-4-4:2012 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 4: Electrical fast transient/burst immunity test

- IEC 61000-4-5:2014+A1:2017 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 5: Surge immunity test
- IEC 61000-4-6:2013 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 6: Conducted immunity test
- IEC 61000-4-8:2009 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 8: Power frequency magnetic field immunity testing
- IEC 61000-4-11:2004+A1:2017 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 11: Voltage dips and interruptions immunity test
- IEC 61000-3-2:2018+A1:2020 - Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current < 16A per phase)
- IEC 61000-3-3:2013+A2:2021 - Electromagnetic compatibility (EMC) - Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current < 16A per phase and not subject to conditional connection
- IEC TS 60601-4-2 Edition 1.0 2024-03 - Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 80601-2-26:2019 – Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs.
- Federal Register CFR 47, Part 15, subpart B Radiated Emissions, Part 15.109(b), Class A
- Federal Register CFR 47, Part 15, subpart B Conducted Emissions, Part 15.107(b), Class A
- AIM 7351731 Rev. 3.00 (2021-06-04) – Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
- FDA Guidance Document - Electromagnetic Compatibility (EMC) of Medical Devices (June 6, 2022) – Section J – Common Electromagnetic (EM) Emitters

- "Electromagnetic compatibility testing of implantable neurostimulators exposed to metal detectors"; The Open Biomedical Engineering Journal, 2010, Volume 4
- "Electromagnetic field strength levels surrounding electronic article surveillance (EAS) systems"; Health Physics Publication 2000

10. Software

Based on the FDA guidance document Content of Premarket Submissions for Device Software Functions issued on June 14, 2023, the sponsor has determined basic documentation level is necessary. In accordance with the guidance, we have submitted the below documents in our submission:

- Documentation Level Evaluation
- Software Description
- Risk Management File
- Software Requirement Specifications (SRS)
- System and Software Architecture Design
- Software Development, Configuration Management, and Maintenance Practices
- Software Testing as Part of Verification and Validation
- Software Version History
- Unresolved Software Anomalies

11.**Cybersecurity:**

The proposed device incorporates cybersecurity controls consistent with FDA guidance to ensure the confidentiality, integrity, and availability of data. The device uses secure communication protocols, encrypted data storage, and authenticated user access to protect against unauthorized access and data breaches. A comprehensive risk assessment and threat mitigation strategy have been implemented, and verification and validation activities demonstrate that the cybersecurity features do not introduce new safety or effectiveness concerns.

12. **Human Factors & Usability**

A Human Factors and usability assessment was conducted in accordance with FDA guidance. Based on the results of the Hazard Analysis and the Use-Related Risk Analysis (URRA), it was determined that there are no critical tasks associated with the operation of the device that could result in harm. Therefore, a formal final Human Factors validation study is not required and will not be conducted. Usability considerations were integrated throughout the design and development process to ensure safe and effective use by intended users in the intended use environment.

13. **Conclusion**

In accordance with 21 CFR Part 807 and based on the information provided in this premarket notification, including the results of nonclinical testing and performance evaluations, we conclude that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices cleared under 510(k) number K945826 and K990538. The technological characteristics and intended use of the subject device are substantially equivalent to those of the predicate device, and no new questions of safety or effectiveness are raised.