August 25, 2025

NeuroEars Inc.
Hannah Taggart
Regulatory Associate
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K243709
Trade/Device Name: NeuroEars-Anna™
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: November 27, 2024
Received: December 2, 2024

Dear Hannah Taggart:

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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243709

Device Name
NeuroEars-Anna™

Indications for Use *(Describe)*
The NeuroEars-Anna™ system provides information to assist in the nystagmographic evaluation, diagnosis, and documentation of vestibular disorders. Nystagmus of the eye is recorded using a head-mounted display equipped with eye-tracking cameras. These images are measured, recorded, displayed, and stored in the software. This information can then be used by trained medical professionals to assist in diagnosing vestibular disorders.

The NeuroEars-Anna™ system is intended for use in individuals aged 12 years and older, based on the physical compatibility of the FOVE VR headset (FOVE Inc., Japan). While the ANSI S3.45 standard does not define age-based limitations, the FOVE VR headset is generally suitable for individuals aged 12 and above. For improved fit, soft materials such as sponge pads may be used in cases where the headset does not conform properly to the user's face. This applies to both pediatric and adult patients. Any additional padding should be used only if it does not interfere with eye-tracking performance or measurement accuracy and must follow the manufacturer's instructions for proper use.

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.

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510(K) SUMMARY

Submitter's Name:	NeuroEars Inc.
Submitter's Address:	(24232) 209-2F, 7, Huseok-ro 462beon-gil Chuncheon-si, Gangwon-do, Republic of Korea
Submitter's Telephone:	+82-10-8919-4380
Contact Person:	Hannah Taggart, MS Empirical Technologies 719- 457-1152 htaggart@empiricaltech.com
Date Summary was Prepared:	August 25, 2025
Trade or Proprietary Name:	NeuroEars-Anna™
Device Classification Name:	Nystagmograph, vestibular analysis
Classification & Regulation #:	Class II per 21 CFR §882.1460
Product Code:	GWN
Classification Panel:	Neurology

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

NeuroEars-Anna™ is a standalone software device that analyzes eye movements to assist medical professionals in the nystagmographic evaluation, diagnosis, and documentation of vestibular disorders. The NeuroEars-Anna™ software is intended to be used with off the shelf hardware including the HMD, PC, and monitors.

The NeuroEars-Anna™ software is designed to perform the following vestibular tests:

- Spontaneous Nystagmus Test
- Gaze-Evoked Nystagmus Test
- Head Shaking Nystagmus Test
- Fistula Nystagmus Test
- Dix-Hallpike Test
- Positional Test
- Smooth Pursuit Test
- Random Saccade Test
- Saccadometry Test
- Optokinetic Nystagmus Test
- Subjective Visual Vertical/Subjective Visual Horizontal (SVV/SVH)
- Caloric Test
- Video Frenzel

The NeuroEars-Anna™ system is to be used by trained personnel only, such as audiologists, ENT surgeons, doctors, hearing healthcare professionals, or personnel with a similar level of qualifications. The device should not be used without the necessary knowledge and training to understand its use and how to interpret the results.

The target population for the NeuroEars-Anna™ system is any individual who can wear the HMD according to the manufacturer's instructions for use.

INDICATIONS FOR USE

The NeuroEars-Anna™ system provides information to assist in the nystagmographic evaluation, diagnosis, and documentation of vestibular disorders. Nystagmus of the eye is recorded using a head-mounted display equipped with eye-tracking cameras. These images are measured, recorded, displayed, and stored in the software. This information can then be used by trained medical professionals to assist in diagnosing vestibular disorders.

The NeuroEars-Anna™ system is intended for use in individuals aged 12 years and older, based on the physical compatibility of the FOVE VR headset (FOVE Inc., Japan**)**. While the ANSI S3.45 standard does not define age-based limitations, the FOVE VR headset is generally suitable for individuals aged 12 and above. For improved fit, soft materials such as sponge pads may be used in cases where the headset does not conform properly to the user's face. This applies to both pediatric and adult patients. Any additional padding should be used only if it does not interfere with eye-tracking performance or measurement accuracy and must follow the manufacturer's instructions for proper use.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicate device:

- Indications for Use
- Intended User Population
- Intended Patient Population
- Technological Characteristics
- Vestibular Tests

Predicate Device

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code
K143607	I-Portal® Neuro Otologic Test Center (NOTC) I-Portal® Video Nystagmography System (VNG) I-Portal® Video Oculography Eye Tracking System (VOG)	Neuro Kinetics, Inc.	GWN

Predicate Comparison Table

	Subject Device	Predicate	Comparison
	NeuroEars-Anna™	**I-Portal Neuro Otologic Test Center (NOTC), I-Portal Video Nystagmography System (VNG), and I-Portal Video Oculography Eye Tracking System (VOG) (K143607)**	
Regulation Number No.	21 CFR 882.1460	21 CFR 882.1460	Same
Product Code	GWN	GWN	Same
Indications for use	The NeuroEars-Anna™ system provides information to assist in the nystagmographic evaluation, diagnosis, and documentation of vestibular disorders. Nystagmus of the eye is recorded using a head-mounted display	**I-Portal® Video-Nystagmography System (VNG)** I-Portal® Video-Nystagmography System (VNG) is used in vestibular and neuro otologic diagnostic testing. The VNG provides stimuli to a patient through visual cues, monitors the patient's response, and	Same. The subject device has the same indications for use as the predicate device but uses a head-mounted display with eye-tracking cameras while the predicate is used with goggles with mounted cameras.

	Subject Device	Predicate	Comparison
	NeuroEars-Anna™	**I-Portal Neuro Otologic Test Center (NOTC), I-Portal Video Nystagmography System (VNG), and I-Portal Video Oculography Eye Tracking System (VOG) (K143607)**	
	equipped with eye-tracking cameras. These images are measured, recorded, displayed, and stored in the software. This information can then be used by trained medical professionals to assist in diagnosing vestibular disorders. The NeuroEars-Anna™ system is intended for use in individuals aged 12 years and older, based on the physical compatibility of the FOVE VR headset (FOVE Inc., Japan**)**. While the ANSI S3.45 standard does not define age-based limitations, the FOVE VR headset is generally suitable for individuals aged 12 and above. For improved fit, soft materials such as sponge pads may be used in cases where the headset does not conform properly to the user's face. This applies to both pediatric and adult patients. Any additional padding should be used only if it does not interfere with eye-tracking performance or measurement accuracy and must follow the manufacturer's instructions for proper use.	presents the data for interpretation by qualified medical personnel trained in vestibular diagnostic testing. This device provides no diagnoses nor does it provide diagnostic recommendations. **I-Portal® Video Oculography (VOG) System** I-Portal® Video Oculography (VOG) System is used to monitor and record eye movements from various stimuli used in vestibular diagnostic testing. The system measures and records horizontal, vertical, and torsional eye movements, as well as pupil area. It is used in conjunction with various stimuli (rotary chair, manual (done by clinician) positional maneuvers, caloric tests, external stimulus) to detect and record nystagmus and eye tracings for interpretation by qualified medical personnel trained in vestibular diagnostic testing. This device provides no diagnoses nor does it provide diagnostic recommendations.	
Description	NeuroEars-Anna™ is a software program that analyzes eye movements recorded from an eye-tracking camera mounted on a head-mounted display (HMD) with eye-tracking specifications suggested by ANSI/ASA S3.45-2009 (Reaffirmed by ANSI April 16, 2024 version). The HMD devices used can be commercial products such as the FOVE0 (powerd by FOVE Inc., Japan), which meet these minimum eye-tracking specifications. The software is intended to run on a Microsoft Windows PC platform.	The I-Portal device functions as a nystagmograph, defined by 21 CFR 882.1460 as "a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball." Through its nystagmograph functionality, the device is indicated for use as a diagnostic tool to assist trained physicians in their analysis of vestibular disorders, which requires the separation of central and peripheral nervous system deficits. The I-Portal is used in an institutional environment on the order of a physician. To achieve safe and effective clinical operation, the I-Portal device uses a battery of tests within a family of products: the NOTC, the VNG, and the VOG. The I-Portal NOTC features a rotational chair, the OKN optical stimulus, the PT laser target generator, the I-Portal VOG, and a test enclosure equipped with a communication system. Through the use of these elements and the VEST™ analysis software, the physician is able to schedule a set of tests isolating oculomotor and vestibular functions to help the physician understand possible vestibular disorders. The I-Portal VNG offers a subset of the NOTC tests and different vestibular tests through a device with a smaller physical footprint. The VNG has many of the same elements used in the NOTC configuration: the OKN optical stimulus, the PT laser target generator, the VOG, and the VEST	Same. The subject device analyzes eye tracking movements and is intended to be run on a Microsoft Windows PC platform like the predicate device.

	Subject Device	Predicate	Comparison
	NeuroEars-Anna™	**I-Portal Neuro Otologic Test Center (NOTC), I-Portal Video Nystagmography System (VNG), and I-Portal Video Oculography Eye Tracking System (VOG) (K143607)**	
		software platform. However, unlike the NOTC, it does not have the rotational chair, and does not utilize the enclosure / communication system, but the VNG can collect and analyze data from caloric and position tests. The VNG configuration is typically used in smaller clinics or conditions requiring device mobility. The third configuration of the NKI I-Portal is a digital eye tracking system – the I-Portal VOG. The VOG is incorporated within the NOTC and VNG configurations; however, the VOG can be used as a stand-alone product with the VEST software, but offering a subset of the tests afforded by either the NOTC or VNG.	
Intended User Population(operator)	The NeuroEars-Anna™ system is to be used by trained personnel only, such as audiologists, ENT surgeons, doctor's, hearing healthcare professionals, or personnel with a similar level of qualifications. The device should not be used without the necessary knowledge and training to understand its use and how to interpret the results.	The modified I-Portal has the same intended use and indications for use as the predicate device cleared per K083603. Both the modified I-Portal and its predicate device are intended to be used as a nystagmograph. The indications for use for the modified I-Portal device and the predicate device cleared per K083603 are identical, and are as follows: NOTC I-Portal® Neuro Otologic Test Center (NOTC) is a rotary chair system used in vestibular and neurootologic diagnostic testing. The NOTC provides stimuli to a patient through motion profiles and/or visual cues, monitors the patient's response, and presents the data for interpretation by qualified medical personnel trained in vestibular diagnostic testing. This device provides no diagnoses nor does it provide diagnostic recommendations. VNG I-Portal® Video-Nystagmography System (VNG) is used in vestibular and neuro otologic diagnostic testing. The VNG provides stimuli to a patient through visual cues, monitors the patient's response, and presents the data for interpretation by qualified medical personnel trained in vestibular diagnostic testing. This device provides no diagnoses nor does it provide diagnostic recommendations. VOG I-Portal® Video Oculography (VOG) System is used to monitor and record eye movements from various stimuli used in vestibular diagnostic testing. The system measures and records horizontal, vertical, and torsional eye movements, as well as pupil area. It is used in conjunction with various stimuli (rotary chair, manual (done byclinician) positional maneuvers, caloric tests, external stimulus) to detect and record	Same

	Subject Device	Predicate	Comparison
	NeuroEars-Anna™	**I-Portal Neuro Otologic Test Center (NOTC), I-Portal Video Nystagmography System (VNG), and I-Portal Video Oculography Eye Tracking System (VOG) (K143607)**	
		nystagmus and eye tracings for interpretation by qualified medical personnel trained in vestibular diagnostic testing. This device provides no diagnoses nor does it provide diagnostic recommendations.	
Intended Patient Population	The target population for the NeuroEars-Anna™ system is any individual who can wear the HMD according to the manufacturer's instructions for use.	18 years and above	The subject device is intended to be used with patients aged 12 and older. The predicate device was intended for ages 18+. The subject device included patients within this age group during clinical study to confirm this difference does not raise any questions for safety and efficacy of the subject device.
Technological characteristics	The NeuroEars-Anna™ system is intended to incorporate various Head mounted goggle with eye tracking camera, FOVE Inc.	The modified I-Portal has identical technological characteristics as the previously cleared predicate IPortal (K083603), with the exception of the following modifications: **User-defined normative data input and display** The addition of user-defined normative data input and display does not alter the raw data or analysis results gathered from the patient. In current clinical practice, users may store normative data ranges in various locations (separate electronic files, written notes) or they may rely solely on their clinical judgment. This feature provides the user with a safe and convenient storage location for this information, as well as a way to easily analyze patient results with respect to the clinician's choice of normal values. By providing this feature, the software will eliminate the need to draw the normal areas by hand on screenshot printouts of every patient graph. Validation testing has been conducted to demonstrate that users can safely and effectively use the I-Portal with user-defined normative data input. **Controlled rotation Head Impulse Test (crHIT)** The crHIT test is a high acceleration inter aural rotation test performed in the I-Portal NOTC chair to examine the high-frequency properties of the peripheral vestibular system. The crHIT test is substantially equivalent to the head thrust test, previously cleared for the predicate device, as both tests collect similar data, include similar calculations, and provide similar outputs. Verification testing confirmed that hardware modifications do not impact the functionality of the I-Portal. Therefore, the addition of crHIT does not raise new questions of safety or effectiveness.	Different. The subject device is intended to be used with a head-mounted display similar to the predicate which is used with head mounted goggles. The predicate device also has a wider range of compatible hardware components. The subject device was tested in verification and validation testing to confirm the FOVE hardware is compatible with the subject software.
Hardware Platform	Commercial head mount goggles with 2D or 3D eye tracking camera FOVE Inc.	Goggles with mounted cameras	Similar. The subject device is intended to be used with a commercially available head

	Subject Device	Predicate	Comparison
	NeuroEars-Anna™	**I-Portal Neuro Otologic Test Center (NOTC), I-Portal Video Nystagmography System (VNG), and I-Portal Video Oculography Eye Tracking System (VOG) (K143607)**	
			mount display while the predicate device is used with goggles mounted with cameras.
Vestibular tests	Calibration	Not Included	N/A
	Spontaneous Nystagmus Test	Spontaneous Nystagmus Test	Same.
	Gaze-Evoked Nystagmus Test	Gaze Nystagmus Vertical and Horizontal	Same.
	Dix-Hallpike Test	Dix-Hallpike Test	Same.
	Positional Test	Positional Test	Same.
	Caloric Test	Caloric Test	Same.
	Smooth Pursuit Test	Smooth Pursuit (CPT 92546) Vertical and Horizontal	Same.
	Random Saccade Test	Random Saccade Test	Same.
	Saccadometry Test	Saccade Vertical and Horizontal	Same.
	Optokinetic Nystagmus Test	Full Field Optokinetic (CPT 92544)	Same.
	Subjective Visual Vertical / Subjective Visual Horizontal (SVV/SVH)	Subjective Visual Vertical and Horizontal	Same.
	Video Frenzel	Video Frenzel	Same.
	Video Recording	Video Recording	Same.
	Head Shaking Nystagmus Test	Head Shaking Nystagmus Test	Same.
	Fistula Nystagmus Test	Not Included	N/A

PERFORMANCE DATA

The NeuroEars-Anna™ was evaluated in performance testing to verify whether the system meets the required performance criteria for conducting Videonystagmography (VNG) in accordance with the ANSI 3S.45 standard.

Performance Testing Results

Performance Test	Acceptance Criteria	Test Results	Pass/Fail
Eye Tracking Camera Frame Rate	• Minimum 60 Hz	• Hardware specification standard 120 Hz	Pass
Eye Tracking Accuracy	• Horizontal error: 0.1° to 1.0°, • Vertical error: 0.4° to 1.0°	• Hardware specification standard: 1.15° median accuracy for uniform distribution across screen (<1 degree in center) • Internal validation results: Error within 1.0°	Pass
Visual Fixation Point Requirements	• The visual fixation point should move in various ways and speeds (0.2 Hz – 0.4 Hz) within a sufficient field of view of approximately 20° horizontally • The visual fixation point should be green-yellow or red	• Internal validation results: The visual fixation point moves in various ways and speeds (0.2Hz – 0.4Hz) within a sufficient field of view of approximately 20° horizontally • Internal validation results: The visual fixation point is red	Pass

The results of this non-clinical testing show and support that the subject device is substantially equivalent to its legally marketed predicate device.

CLINICAL STUDY

The NeuroEars-Anna™ was tested side by side with its predicate device across multiple oculomotor tests. The results of these tests confirm that the NeuroEars-Anna™ provides clinically reliable and equivalent measurements compared to the predicate and is therefore suitable for use in vestibular and neuro-otologic evaluations, with validated normative data and performance metrics supporting its intended diagnostic application.

CONCLUSION

The overall technological characteristics and mechanical performance data lead to the conclusion that the NeuroEars-Anna™ is substantially equivalent to the predicate device.