June 12, 2026

VoxNeuro, Inc.
Andrew Matiasso
Director of Clinical Operations
121 King St. W Suite 2150
Toronto, Ontario M5H 3T9
Canada

Re: K253015
Trade/Device Name: Cognitive Function Neuroimaging (cfNI) Software (1.0.0)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLU
Dated: May 13, 2026
Received: May 14, 2026

Dear Andrew Matiasso:

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 13484 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 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 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,

JAY R. GUPTA -S

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253015

Please provide the device trade name(s).

Cognitive Function Neuroimaging (cfNI) Software (1.0.1)

Please provide your Indications for Use below.

The Cognitive Function Neuroimaging (cfNI) software is to be used by qualified healthcare professionals for the digital post-hoc statistical analysis of the human electroencephalogram (“EEG”), including event-related potentials (“ERPs”). This device is indicated for use in individuals 18 to 70 years of age, and in conjunction with Resting State, Auditory Oddball, Go No-Go, Continuous Visual Memory Test, and Eriksen Flanker tasks.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

1. SUBMITTER INFORMATION

Applicant:	VoxNeuro Inc. 121 King St. W Suite 2150, Toronto, ON M5H 3T9
Contact:	Andrew Matiasso Director of Clinical Operations +1 647-220-4586 andrew.matiasso@voxneuro.com
Date Prepared:	May 13, 2026

2. SUBJECT DEVICE

Device Trade Name:	Cognitive Function Neuroimaging (cfNI) Software
Device Common Name:	Normalizing Quantitative Electroencephalograph Software
Regulation Number:	21 CFR 882.1400
Regulatory Class:	Class II
Product Code:	OLU

3. PREDICATE DEVICE

Predicate Device:	BNA Platform (K202588) Firefly Neuroscience; formerly elminda Ltd.

4. DEVICE DESCRIPTION

The Cognitive Function Neuroimaging (cfNI) software is to be used by qualified healthcare professionals for the digital post-hoc statistical analysis of the human electroencephalogram ("EEG"), including event-related potentials ("ERPs"). This device is indicated for use in individuals 18 to 70 years of age, and in conjunction with Resting State, Auditory Oddball, Go No-Go, Continuous Visual Memory Test, and Eriksen Flanker tasks.

The cfNI software compares EEG measures to a reference database and produces an outcome report to support interpretation by a qualified user. This includes measures that are typical for technologies regulated under product code OLU (e.g., event-related potentials (ERPs), power, frequency ratios, etc.). The cfNI software system also includes functionality for EEG data acquisition and synchronized auditory/visual stimulus presentation, enabling the user to acquire and record the synchronized EEG and stimulus-response input data necessary for downstream processing and analysis.

The device does not provide a diagnosis or clinical interpretation. It is for prescription-use only.

5. INTENDED USE / INDICATIONS FOR USE

The Cognitive Function Neuroimaging (cfNI) software is to be used by qualified healthcare professionals for the digital post-hoc statistical analysis of the human electroencephalogram ("EEG"), including event-related potentials ("ERPs"). This device is indicated for use in individuals 18 to 70 years of age, and in conjunction with Resting State, Auditory Oddball, Go No-Go, Continuous Visual Memory Test, and Eriksen Flanker tasks.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

The Cognitive Function Neuroimaging (cfNI) software device and predicate device are both indicated for the digital post-hoc statistical analysis of the human electroencephalogram ("EEG"), including event-related potentials ("ERPs"). The software is to be used by qualified healthcare professionals in both the subject and predicate devices.

The cfNI device's indicated age range across tasks is 18-70 years of age, while the predicate device's age range across tasks is 12–85 years. The cfNI software device is to be used with Resting State (eyes open), Auditory Oddball, Go No-Go (auditory), Continuous Visual Memory Test (CVMT), and Eriksen Flanker tasks. The predicate utilizes three of the same tasks; Resting State (eyes closed), Auditory Oddball, and Go No-Go (visual) tasks. The predicate device does not, however, include the other two well-established tasks included in the subject device (i.e., CVMT, and Eriksen Flanker tasks). The two additional tasks utilized in the subject device employ the same conventional ERP acquisition and analysis methods utilized in the three

congruent tasks. That is to say, the methodology of using a well-established task to elicit a response (i.e., ERP), recording that synchronized EEG and stimulus-response data, analyzing it, and normalizing it for qualified user interpretation is maintained in these two additional tasks. Like the congruent tasks, the additional tasks are well-established in cognitive neuroscience, and are based on validated task designs from the scientific literature. Clinical testing data demonstrates that the cfNI device safely and effectively quantifies conventional EEG and ERP parameters across all age-bins, tasks, and outcome measures, as established through normalization method validation, poolability analysis, and reliability testing. These results do not raise new questions of safety or effectiveness in comparison with the predicate device.

In summary, these differences reflect a slight expansion in application of the predicate device's established methodology, similar to how the predicate expanded the tasks used when demonstrating equivalency to their predicate (K121119). None of the differences between the subject and predicate devices change the core methodology or principle of operation, or raise different questions of safety or effectiveness.

Technological Comparison

The table below compares the key technological features of the cfNI Software (subject device) to the BNA Platform (predicate device; K202588).

Table 1: Technological Comparison

	cfNI Software (Subject Device)	BNA Platform (Predicate Device)	Discussion
Manufacturer	VoxNeuro	elminda Ltd.	-
510(k) Number	K253015	K202588	-
Regulation Number	882.1400	882.1400	Same as predicate.
FDA Device Class	Class II	Class II	Same as predicate.
Product Code	OLU	OLU	Same as predicate.
Intended Patient Population	18-70 years of age (all tasks).	12-85 years of age (Resting State, Auditory Oddball). 25-85 years of age (Go No-Go)	Subject device narrows the age range (18-70). Clinical testing data demonstrates substantial equivalence.

Indications for Use	The Cognitive Function Neuroimaging software is to be used by qualified healthcare professionals for the digital post-hoc statistical analysis of the human electroencephalogram (“EEG”), including event-related potentials (“ERPs”). This device is indicated for use in individuals 18 to 70 years of age, and in conjunction with Resting State, Auditory Oddball, Go No-Go, Continuous Visual Memory Test, and Eriksen Flanker tasks.	The BNA Platform is to be used by qualified medical professionals for the post-hoc statistical analysis of the human electroencepholagram ("EEG"), including event-related potentials ("ERPs"). This device is indicated for use in individuals 12-85 years of age. The BNA Platform is to be used with the Auditory Oddball, Visual Go No-Go (age range of 25 to 85 years), and Eyes-Closed tasks.	Subject device narrows the age range (18-70), and includes two additional well-established tasks. Clinical testing data demonstrates substantial equivalence.
Intended User	Qualified healthcare professionals	Qualified medical professionals	Same as predicate.
Principle of Operation	Performs post-hoc statistical analysis of artifact-free EEG data acquired from subject device, with automatic algorithmic analysis, normalization, and report generation. Acquisition of EEG data is performed by acquisition and task delivery modules within the subject device, defined within the system’s principle of operation.	Performs post-hoc statistical analysis of artifact-free EEG data imported from third party device, with automatic algorithmic analysis, normalization, and report generation. Acquisition of EEG data is performed externally and is not addressed within the regulated system’s principle of operation.	Subject device software includes integrated modules for data acquisition and task delivery instead of importing data from third-party acquisition system.
Interoperability	Requires input data acquired from third party devices / components (i.e., EEG amplifiers, electrodes, task delivery peripherals, host computer).	Requires input data acquired from third party devices / components (i.e., EEG amplifiers, electrodes, task delivery peripherals, host computer).	Same as predicate.
Typical Biopotential Signals Analyzed	Electroencephalography (EEG), evoked brain responses (ERP), and task-response behavioral data.	Electroencephalography (EEG), evoked brain responses (ERP), and task-response behavioral data.	Same as predicate.

Tasks Utilized	Resting-State Auditory Oddball (AOB) Go No-Go (GNG) Continuous Visual Memory Test (CVMT) Eriksen Flanker	Resting-State Auditory Oddball (AOB) Go No-Go (GNG)	Subject device adds two additional well-established tasks. Clinical testing data demonstrates substantial equivalence.
EEG Spectral Analysis	Power spectral density analysis into 4 frequency bands (delta, theta, alpha, and beta)	Power spectral density analysis into 4 frequency bands (delta, theta, alpha, and beta)	Same as predicate.
EP/ERP Waveform Extraction	Time-domain averaging of artifact free epochs across relevant EEG channels.	Time-domain averaging of artifact-free epochs across relevant EEG channels.	Same as predicate.
EP/ERP Peak selection	Peak-detection at the level of the decomposed ERP is performed on the average of the relevant electrodes.	Peak-detection at the level of the decomposed ERP is performed on the highest peak of the relevant electrodes.	Equivalent: Subject device selects peak on the average of electrodes instead of highest peak.
Comparison to Reference Database	Yes. EEG / ERP data is compared to age-matched bin for each of the tasks utilized.	Yes. EEG / ERP data is compared to age-matched bin for each of the tasks utilized.	Same as predicate.
Reference Database Size & Composition	Database consists of 544 subjects spanning age range of 18-70.	Database consists of 1900 subjects spanning age range of 12-85.	Equivalent: Both devices include reference databases that have been assessed and found to meet applicable acceptance criteria across the age range of the intended use population.

Database Age Bins / Stratification	Database stratifies reference data into same number of bins, regardless of task: ALL Tasks (3 bins) 18-34, 35-54, 55-70	Database stratifies reference data into different number of bins depedning on task: Auditory Oddball (AOB) task (9 bins): 12–14, 14–16, 16–18, 18–25, 25–35, 35–50, 50–65, 65–75, 75–85 Visual Go/No-Go (VGNG) task (5 bins): 25–35, 35–50, 50–65, 65–75, 75–85 Eyes-Closed Resting EEG (many bins): 133 overlapping bins at 0.5-year resolution across 12–85 years	Equivalent: Both devices enable age-matched comparisons to reference database data.
Visual Display of ERPs	Displays broadband and band-pass filtered ERP waveforms. Standardized scores for amplitude and latency are shown alongside waveform plots and topographies. Maximal peaks are highlighted.	Displays broadband and band-pass filtered ERP waveforms. Standardized scores for amplitude and latency are shown alongside waveform plots and topographies. Maximal peaks are highlighted.	Same as predicate.
Visual Display of EEG	Yes; the following scores are extracted from power spectral density and displayed on the outcome report: Relative Power, and Frequency Ratios.	Yes; the following scores are extracted from power spectral density and displayed on the outcome report: Absolute and Relative Power, Individual Alpha Frequency, Hemispheric Asyemmetry, and Frequency Ratios.	Same as predicate for measures included in subject device's outcome report.
Software Architecture	Cloud-hosted SaMD architected using AWS cloud infrastructure.	Cloud-hosted SaMD architected using AWS cloud infrastructure.	Same as predicate.

7. PERFORMANCE DATA SUMMARY

Non-Clinical Testing

The cfNI device underwent comprehensive software verification and validation (V&V) in alignment with IEC 62304:2006 (Class B), ISO 14971:2019, and FDA's General Principles of Software Validation. Verification, utilizing methods such as testing and inspection, ensured all functional and non-functional requirements were safely and effectively implemented, with all tests passing. Validation confirmed the fully integrated system met intended use and user needs under simulated clinical conditions, encompassing data acquisition, task execution, interoperability, report generation, data processing, cybersecurity, and installation integrity. All validation activities were conducted by representative users in production-like environments, meeting all acceptance criteria.

Nonclinical performance testing of the system's ability to synchronize stimulus event signals with the continuous EEG signal was also performed. In this testing, software trigger synchronization accuracy performance testing was assessed in the specific software module used to synchronize stimuli events and EEG signals. This was done across three event types: auditory stimuli, visual stimuli, and keypress events. The validation setup involved hardware-based ground truth capture using signals derived from photodiodes and hardware that converts analog signals into digital signals, enabling precise measurement of trigger timing relative to actual stimulus or response onset. Each experimental condition was repeated multiple times per system, and performance was quantified in terms of offset (i.e., systematic temporal deviation between the software and hardware triggers, a consistent shift) and jitter (i.e., the random variability in trigger alignment, an unpredictable variability). Performance outcomes were demonstrated to be acceptable and well within the range of required synchronization timing for time-critical applications in neurophysiology (i.e., ERPs).

Clinical Testing

Clinical testing was performed to support a determination of substantial equivalence between the cfNI software device and the predicate device (K202588) with respect to each of their abilities to quantify and normalize EEG and ERP measures, evaluated through normalization method validation, poolability analysis, and reliability testing.

A total of 544 healthy adult participants (ages 18–70 years) were recruited across multiple sites in the U.S. and Canada. Participants were stratified across 3 age-group bins (18-34, 35-54, 55-70) representing distinct periods in adult maturation and aging. Participants completed an EEG assessment involving synchronized auditory and visual stimulus presentation during standardized task paradigms designed to elicit event-related potentials (ERPs). Tasks included Resting State, Auditory Oddball, Go No-Go, Continuous Visual Memory Test, and Eriksen Flanker. Acquired EEG and stimulus-response data were processed using notch filtering, artifact rejection, baseline correction, spectral analysis, ERP waveform extraction, and ERP peak selection. Subject-level features (ERP amplitude, ERP latency, behavioral task performance metrics, and spectral band power) were obtained and used for population-level statistical analysis.

Collectively, the results from nonclinical and clinical testing demonstrate that the cfNI software device is substantially equivalent in safety and effectiveness as the predicate device.

8. CONCLUSION

Based on the detailed comparison to the predicate devices, the performance testing, and the clinical testing, the cfNI Software device can be found substantially equivalent to the predicate device.