September 20, 2024

NeuroField Inc.
℅ Tom Renner
Quality, Efficiency & Regulatory Affairs Consultant
Vision28
915 SW Rimrock Way
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Re: K240420
Trade/Device Name: NeuroField Analysis Suite
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLU, GWJ
Dated: February 13, 2024
Received: February 13, 2024

Dear Tom Renner:

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,

FDA Patrick Antkowiak -S

for
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

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)*
K240420

Device Name
NeuroField Analysis Suite

Indications for Use *(Describe)*
The NeuroField Analysis Suite is to be used by qualified medical and qualified clinical professionals for the display and storage of electrical activity of a patient's brain, including the post-hoc statistical evaluation of the human electroencephalogram (EEG) and event-related potentials (ERP).

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 - K240420

Contact Details

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Date Prepared: September 19, 2023

Device Name

Trade Name: NeuroField Analysis Suite
Product Code: OLU, GWJ
Common and Classification Name: Electroencephalograph
Classification Regulation: 21 CFR 882.1400
Product Class: Class II

Legally Marketed Predicate Device

510(k)	Product Code	Trade Name	Applicant
K041263	OLU	NeuroGuide Analysis System	Applied Neuroscience, Inc. 228 176th Terrace Drive St. Petersburg, Florida 33708

Legally Marketed Secondary Predicate Device

510(k)	Product Code	Trade Name	Applicant
K171781	GWJ	eVox System	Evoke Neuroscience, Inc. 200 Valencia Dr. Suite 109 Jacksonville, North Carolina 28546

Device Description

I. Overview

The NeuroField Analysis Suite is a Normalizing Quantitative Electroencephalograph (QEEG) Software that can (1) execute EEG analysis and (2) conduct ERP test and ERP analysis. The NeuroField Analysis Suite is Software as a Medical Device (SaMD).

II. Major Components

The NeuroField Analysis Suite consists of two modules, the NF EEG Analysis Module and the NF ERP Module.

The NF EEG Analysis Module is a separate analysis module that integrates with the Q21 EEG system by adding "Analysis", "Report", and "Tools" menu items and toolbars. It performs real-time and offline analysis functions and displays analysis results in separate windows in the UI, which can be accessed via the "Analysis" and "Reports" menu items.

The NF ERP Module is a separate evoked response potential (ERP) module that can control and get data from the Q21 EEG system and performs typical ERP functions like stimulus presentation, EEG epoching, epoch averaging, reaction time, and ERP display. The NF ERP Module is a separate stand-alone application.

Intended Use/Indications for use

The NeuroField Analysis Suite is to be used by qualified medical and qualified clinical professionals for the display and storage of electrical activity of a patient's brain, including the post-hoc statistical evaluation of the human electroencephalogram (EEG) and event-related potentials (ERP).

Substantial Equivalence Comparison

Based upon comparisons of regulatory parameters, features, and performance evaluations, the NeuroField EEG Analysis module of the NeuroField Analysis Suite is substantially equivalent to the primary predicate device, NeuroGuide Analysis System (K041263), and the NeuroField ERP functions are substantially equivalent to the secondary predicate device, eVox System (K171781).

The comparison between the NeuroField Analysis Suite, the primary predicate NeuroGuide Analysis System (K041263) and the secondary predicate eVox System (K171781) below consists of a series of tables followed by explanations of the similarities and differences described in each table.

III. Comparison of Regulatory Parameters

Comparison	NeuroField Analysis Suite	Primary Predicate: NeuroGuide Analysis System (K041263)	Secondary Predicate: eVox System (K171781)

Indications for use	*The NeuroField Analysis Suite is to be used by qualified medical and qualified clinical professionals for the display and storage of electrical activity of a patient's brain, including the post-hoc statistical evaluation of the human electroencephalogram (EEG) and event-related potentials (ERP).*	**The NeuroGuide Analysis system is to be used by qualified medical and qualified clinical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG).**	The eVox System is intended for the acquisition, **display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP)** obtained by placing two or more electrodes on the head to aid in diagnosis.
Intended population	Patients of all ages.	Patients of all ages ("2 months to 82 years").	All age groups.
Common or usual name	Normalizing Quantitative Electroencephalograph Software Stimulator, Auditory, Evoked Response	Normalizing Quantitative Electroencephalograph Software	Full Montage Electroencephalograph Stimulator, Auditory, Evoked Response
Regulatory Class	Class II	Class II	Class II
Classification name and product code	882.1400 Electroencephalograph OLU 882.1900 Evoked response auditory stimulator GWJ	882.1400 Electroencephalograph OLU	882.1400 Electroencephalograph GWQ 882.1900 Evoked response auditory stimulator GWJ

Discussion of Similarities and Differences

The NeuroField Analysis Suite and the primary predicate are materially the same in regulatory parameters:

- Both are Normalizing Quantitative Electroencephalograph Software that can be used with all ages of patients
- Both are for statistical evaluation of the human electroencephalogram (EEG)
- Both have the same classification name, primary product code, and regulatory class

The Indications for Use of the NeuroField Analysis Suite consist of a combination of the Indications for use of the predicate ("**The NeuroGuide Analysis system is to be used by qualified medical and qualified clinical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG).**") and the relevant section of the Indications for Use of the secondary predicate ("**display, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and event-related potentials (ERP)**".

The secondary predicate is provided because of its event-related potentials (ERP) features, compared below.

IV. Comparison of Features – EEG Analysis (OLU)

Category	Comparison	NeuroField Analysis Suite	Primary Predicate: NeuroGuide Analysis System (K041263)
General	Default File Format	Proprietary nfx format	Proprietary ng format
	Supported Open File Standards	EDF, EDF+, XDF	EDF, EDF+
	Supported Device and Vendors	Neurofield Q21	Neurofield Q21 and various other vendors
	Re-montaging	Yes	Yes
	IIR Filtering	Yes	Yes
	Notch Filtering	Yes	Yes
	Add Event Markers	Yes	Yes
	Analyze Whole Data	Yes	Yes
	Analyze Selected Interval	Yes	Yes
	Analyze Selected Markers only	Yes	No
Power Analysis	Absolute Power Raw/Z-Scores	Yes	Yes
	Relative Power Raw / Z-Scores	Yes	Yes
	Power Ratios Raw / Z-Scores	Yes	Yes
	Head Maps	Yes	Yes
	FFT Spectrum	Yes	Yes
	Frequency Resolution	0.5 Hz	0.5 Hz
	Single Frequency Side-Lobe	< -60 dB	First Sidelobe at -45 dB
	Tabular Export or View	Yes	Yes
	Automated Report	Yes	Yes

LORETA	Model	Key Institute 2394 Voxel LORETA Model	Key Institute 2394 Voxel LORETA Model
	Atlas	Brodmann	Brodmann
	3-D Cortex View	Yes	Yes (through NeuroNavigator Add-on)
	Current Density – Raw	Yes	Yes
	Current Density – Z Scores	No	Yes
	Absolute Power – Raw	Yes	Yes
	Absolute Power – Z Scores	No	Yes
	Coherence / Phase Metrics	No	Yes

Discussion of Similarities and Differences

The NeuroField Analysis Suite and the primary predicate are substantially equivalent with respect to the implementation of most standard Quantitative Electroencephalograph Software features, including:

- Both perform re-montaging, filtering, adding event markers, and analysis based upon markers or whole data.
- Both generate Z-Scores for absolute power and relative power of EEG bands or individual frequencies.
- Both generate head maps and FFT spectra, and with equivalent frequency resolution.
- Both provide for tabular export and automated report generation.
- Both can calculate the inverse solution (using the standard LORETA Key Institute 2394 LORETA model) and generate the current densities and powers of the ROIs (Region of Interest) over the cortex using the Brodmann Atlas.
- Both can read standard EDF and EDF+ files.

The two systems differ with respect to file format support and LORETA Z-scoring:

- The NeuroField Analysis Suite can read/export XDF files in addition to EDF / EDF+ files.
- The predicate can read various proprietary EEG file formats from EEG amplifier vendors.
- The predicate generates Z-Scores for the LORETA solution and calculates coherence and phase metrics between the regions.

These differences are minor, and do not materially affect their substantial equivalence with respect to technological basis or use.

V. Comparison of Features – ERP Analysis (GWJ)

Comparison	NeuroField Analysis Suite	Secondary Predicate: eVox System (K171781)	Comment
ERP Stimulus Modality	Auditory; Visual	Auditory; Visual	
ERP Paradigm (Auditory and Visual Stimuli)	P300 Oddball - Single Stimulus Simple Go/No-Go Cued Go/No-Go Active	P300 Oddball - Single Stimulus - Single Deviant - 2 Deviant - Active and Passive	
ERP Task Response	Mouse click	User Buttons	
Number of Signal Recording Channels	Up to 38	Up to 21	
Recording Channels Location and Positioning Systems	Consistent with the 10-20 System	Fz, Cz, Pz, F3, P3, F4, P4 Utilizing elastic bands using distance ratios consistent with the 10-20 System	
Impedance Test	Yes	Yes	
Interface with Amplifier	USB-CAN	Class 2 Bluetooth version 2.0 to PC	
Filtering	User Definable for Visual inspection of the EEG in the 0.1 – 128 Hz range. The underlying software always retains and saves the unfiltered data so that it can be visualized under various filtering settings during postprocessing.	0.1 to 50 Hz	
Audio Frequency Range	500 Hz, 1 kHz, user definable. NF-ERP uses the operating system capabilities to generate the audio. Therefore, the	440Hz-16kHz	NF ERP module has default 500 Hz and 1 kHz audio stims. These stims can be altered by the user.

	clinician user can change the stimulus waveform. The default is: No-Go Stimulus: 500 kHz, Go Stimulus: 1 kHz		The eVox system generates a sound with a frequency range of 440Hz-16kHz which is a sufficiently wide enough band for human hearing.
Audio Intensity	User computer volume setting	0 to 85dB	
Technological Differences in how users administer and set tasks for evoked response stimulation	NF-ERP uses the computer system clock, and the microsecond time stamps on the USB-CAN interface to time lock (synchronize) EEG data samples, stimuli and the user responses. NF-ERP uses computer mouse to record user responses.	Specific details of the eVox system are proprietary to the manufacturer. Based on the available data: The eVox system, like NF-ERP, uses custom software specifically designed to present stimuli (auditory or visual) to the patient. The software controls the timing of stimulus presentation and sends triggers to the EEG acquisition system ensuring millisecond accuracy. eVox system uses USB-based triggering to record user events (response button)	Both systems use similar technologies for time locking and user events.
User-defined Task Parameters	- ERP Paradigm (Visual or auditory) – see above - Active ERP (user always responds to the Go stimuli) - Enable / Disable Warning Stimulus - Enable / disable ripple effect on the stimuli (for	- ERP Paradigm (Visual or auditory)- see above - Active or Passive ERP - Volume Setting	Both systems use similar technologies for time locking and user events. It is not clear in the eVox documentation whether it uses use adjustable stimulus period, number of

	Simple Go-No/Go paradigm) - Stimulus period (for oddball paradigm) - Go stimulus probability - Number of cycles - Task page background color. Volume Setting		cycles, or Go stimulus probability.

The NeuroField ERP module and the secondary predicate are substantially equivalent with respect to the implementation of most standard ERP features, including:

- Both generate averaged ERP graphs for the EEG channels, allowing the user to measure the latency and magnitude of the evoked potentials.
- Both allow for customizable session length.
- Both apply the auditory and visual oddball paradigm, where the user is presented with a periodic common stimuli and the frequency or the duration (in the case of auditory stimulus) or the image (in the case of visual stimuli) is altered infrequently, making it the oddball.
- Both allow the user to set parameters for the visual and auditory oddball paradigm.

The two systems differ in a few ways:

- In the Neurofield ERP Module, the filtering is user definable, whereas in eVox system, it is fixed to a 0.1 - 50 Hz bandpass.
- The Neurofield ERP module interface with the device is USB-CAN, whereas the eVox System uses Bluetooth.
- The Neurofield ERP module uses standard 19-channels, whereas eVox uses only a subset of the standard (7 channels).

These differences are minor, and do not materially affect their substantial equivalence with respect to technological basis or use.

VI. Comparative Performance Evaluations

NF EEG Analysis module and Neuroguide perform similar QEEG analysis on Eyes Closed and Eyes Open task recorded EEG data. Both programs generate Z-Scores for absolute power and relative power of EEG bands or individual frequencies. They can also calculate the inverse solution (using the standard LORETA Key Institute 2394 LORETA model) and generate the current densities and powers of the ROIs (Region of Interest) over the cortex using the Brodmann Atlas. They can read standard EDF and EDF+ files. NF EEG, like Neuroguide, can read/export EDF/EDF+ files. NF-EEG also has XDF file format support. On

the other hand, Neuroguide can read various proprietary EEG file formats from EEG amplifier vendors.

Comparative performance evaluations showed that the same EDF file, loaded to NF-EEG and Neuroguide shows comparable signals on the EEG Plot. When the spectrums are calculated, the result from both programs shows comparable spectrum and sidelobes both for real and simulated data. Both programs show comparable Z-Scores. The visualization of headmaps in both programs also shows comparable topographies over the standard EEG bands. Therefore, NF-EEG demonstrates a comparable performance to the predicate device.

NF ERP Module and eVox System perform similar ERP recording and analysis. Both programs can generate averaged ERP graphs for the EEG channels, allowing the user to measure the latency and magnitude of the evoked potentials. Both programs apply variations of the oddball paradigm, where the user is presented with a periodic common stimulus and the frequency or the duration (in the case of auditory stimulus) or the image (in the case of visual stimuli) is altered infrequently, making it the oddball. In the Neurofield ERP Module, more parameters are user-definable, like the visual filtering, oddball period, Go probability. Clinician also can customize the audio or visual stims. Also, Neurofield ERP module uses 10-20 standard 19-channels or 38- channels, whereas eVox uses a subset of the standard (7 channels).

Since an ERP test requires perfect synchronization between the stimulus time recording and EEG data, comparative performance evaluations were not performed directly between the Neurofield ERP and eVox systems. Instead, a mathematical validation of NF-ERP was performed. This mathematical assessment shows that the generated averaged ERPs are mathematically correct. Moreover, the analysis of real data shows that the NF-ERP can elicit correct ERP components, the generated stimulus is reliable, and the split-half reliability measure confirms test re-test reliability. As a result, the NF-ERP and eVox systems will both produce comparable, mathematically correct oddball ERPs, and the NF-ERP performs that task as well as the predicate device.

VII. Clinical Performance Evaluations

Clinical performance evaluations are not necessary to demonstrate substantial equivalence to the predicate device.

VIII. Conclusion

The devices have materially the same indications for use and the same classifications. They have most of the same features. They are used on the same populations. The two products are different in minor ways that do not materially affect their technological basis or use.

Based upon comparisons of regulatory parameters, features, and performance evaluations, the NeuroField Analysis Suite is substantially equivalent to the primary predicate device,

NeuroGuide Analysis System (K041263), and the NeuroField ERP functions are substantially equivalent to the secondary predicate device, eVox System (K171781).