



May 23, 2025

LVIS Corporation
Sweta Srivastava
Head of Regulatory Affairs
2600 East Bayshore Road
Palo Alto, California 94303

Re: K250239

Trade/Device Name: NeuroMatch
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB, OLT, OMA, OLX
Dated: April 23, 2025
Received: April 24, 2025

Dear Sweta Srivastava:

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,

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

Submission Number (if known)

K250239

Device Name

NeuroMatch

Indications for Use (Describe)

1. LVIS NeuroMatch Software is intended for the review, monitoring and analysis of electroencephalogram (EEG) recordings made by EEG devices using scalp electrodes and to aid neurologists in the assessment of EEG. The device is intended to be used by qualified medical practitioners who will exercise professional judgement in using the information.
2. The Seizure Detection component of LVIS NeuroMatch is intended to mark previously acquired sections of adult EEG recordings from patients greater than or equal to 18 years old that may correspond to electrographic seizures, in order to assist qualified medical practitioners in the assessment of EEG traces. EEG recordings should be obtained with a full scalp montage according to the electrodes from the International Standard 10-20 placement.
3. The Spike Detection component of LVIS NeuroMatch is intended to mark previously acquired sections of adult EEG recordings from patients ≥ 18 years old that may correspond to spikes, in order to assist qualified medical practitioners in the assessment of EEG traces. LVIS NeuroMatch Spike Detection performance has not been assessed for intracranial recordings.
4. LVIS NeuroMatch includes the calculation and display of a set of quantitative measures intended to monitor and analyze EEG waveforms. These include Artifact Strength, Asymmetry Spectrogram, Autocorrelation Spectrogram, and Fast Fourier Transform (FFT) Spectrogram. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms.
5. LVIS NeuroMatch displays physiological signals such as electrocardiogram (ECG/EKG) if it is provided in the EEG recording.
6. The aEEG functionality included in LVIS NeuroMatch is intended to monitor the state of the brain.
7. LVIS NeuroMatch Artifact Reduction (AR) is intended to reduce muscle and eye movements, in EEG signals from the International Standard 10-20 placement. AR does not remove the entire artifact signal and is not effective for other types of artifacts. AR may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified medical practitioner trained in recognizing artifacts, and any interpretation or diagnosis must be made with reference to the original waveforms.
8. LVIS NeuroMatch EEG source localization visualizes brain electrical activity on a 3D idealized head model. LVIS NeuroMatch source localization additionally calculates and displays summary trends based on source localization findings over time.
9. This device does not provide any diagnostic conclusion about the patient's condition to the user.

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
PRASStaff@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**Applicant Information:**

LVIS Corporation
2600 E. Bayshore Rd.,
Palo Alto, CA 94303

Contact Person:

Sweta Srivastava
Head of Regulatory Affairs
Email: ssrivastava@lviscorp.com
Phone: 415-997-7337

Device Information:

Trade Name:	NeuroMatch
Common Name:	Automatic Event Detection Software For Full-Montage Electroencephalograph
Classification Name:	Electroencephalograph (21CFR 882.1400)
Device Class:	II
Product Code:	OMB, OLT, OMA,OLX

Predicate Device:

Epilog PreOp, K172858

Reference Device:

Neurosoft CURRY Multimodal Neuroimaging Software, K001781

Date Prepared:

January 24, 2025

Device Description:

NeuroMatch is a cloud-based software as a medical device (SaMD) intended to review, monitor, display, and analyze previously acquired and/or near real-time electroencephalogram (EEG) data from patients greater than or equal to 18 years old. The device is not intended to substitute for real-time monitoring of EEG. The software includes advanced algorithms that perform artifact reduction, seizure detection, and spike detection.

The subject device is identical to the NeuroMatch device cleared under K241390, with exception of the following additional features:

1. Source localization;
2. Source localization trends;

Source localization and source localization trends are substantially equivalent to the Epilog PreOp (K172858). Apart from the proposed additional software changes and associated changes to the Indications

for Use and labeling there are no changes to the intended use or to the software features that were previously cleared. Below is a description of the software functions that will be added to the cleared NeuroMatch Device.

1. Source Localization

The NeuroMatch Source Localization visualization feature is used to visualize recorded EEG activity from the scalp in an idealized 3D model of the brain. The idealized brain model is based on template MR images. Each single sample of EEG-measured brain activity corresponds to a single point/pixel referred to as a source localization node (i.e., “node”). Together, the source localization nodes form a 3D cartesian grid where EEG signals with higher standardized current density are depicted in red and signals with lower standardized current density are depicted in blue. Source localization can be performed for any selected segment of the EEG data. The maximum and minimum of the source localization values are the absolute maximum and minimum values across the selected EEG signal, respectively. Users can also set an absolute threshold for the minimum value of the source localization outputs.

2. Source Localization Trends

NeuroMatch provides three automatic source localization trends to assist physicians investigating the amplitude and the frequency of the signal of interest (e.g. seizure onset) at the source space. Two of the trends provide simple 3D views of the sources of the high amplitude / high frequency across the signal of interest. The third trend provides a similar 3D view of the high frequency source movement across time.

- **Maximum Amplitude Projection (MAP):** This metric allows clinicians to readily determine which brain regions are active and have high amplitude source localization results. The metric is determined by iterating through each node within a specified analysis time window and outputting the maximum source localization amplitude at that node within the specified analysis time window. No value is reported for nodes which have not been identified as maximum at any time during the specified window. This metric can help show brain regions that have high amplitude during a seizure.
- **Node Visit Frequency (NVF):** This metric is reported as the number of times that a node has been labeled as maximum over time. This metric can help clinicians identify which brain regions are frequently active during a seizure.
- **Node Transition Frequency (NTF):** This metric allows clinicians to determine which brain regions are active in consecutive time frames over a selected time period. A node transition is defined as a transition from one maximum point to another over time, and the node transition frequency is calculated by iterating through all time points for a specified analysis window, counting the number of times a transition between two points occurs over that time, and then dividing it by the time window of analysis. This metric can help identify pairs of brain regions that are frequently active in sequential order.

Indications for Use:

1. LVIS NeuroMatch Software is intended for the review, monitoring and analysis of electroencephalogram (EEG) recordings made by EEG devices using scalp electrodes and to aid neurologists in the assessment of EEG. The device is intended to be used by qualified medical practitioners who will exercise professional judgement in using the information.
2. The Seizure Detection component of LVIS NeuroMatch is intended to mark previously acquired sections of adult EEG recordings from patients greater than or equal to 18 years old that may correspond to electrographic seizures, in order to assist qualified medical practitioners in the assessment of EEG traces. EEG recordings should be obtained with a full scalp montage according to the electrodes from the International Standard 10-20 placement.
3. The Spike Detection component of LVIS NeuroMatch is intended to mark previously acquired sections of adult EEG recordings from patients ≥ 18 years old that may correspond to spikes, in order to assist qualified medical practitioners in the assessment of EEG traces. LVIS NeuroMatch Spike Detection performance has not been assessed for intracranial recordings.
4. LVIS NeuroMatch includes the calculation and display of a set of quantitative measures intended to monitor and analyze EEG waveforms. These include Artifact Strength, Asymmetry Spectrogram, Autocorrelation Spectrogram, and Fast Fourier Transform (FFT) Spectrogram. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms.
5. LVIS NeuroMatch displays physiological signals such as electrocardiogram (ECG/EKG) if it is provided in the EEG recording.
6. The aEEG functionality included in LVIS NeuroMatch is intended to monitor the state of the brain.
7. LVIS NeuroMatch Artifact Reduction (AR) is intended to reduce muscle and eye movements, in EEG signals from the International Standard 10-20 placement. AR does not remove the entire artifact signal and is not effective for other types of artifacts. AR may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified medical practitioner trained in recognizing artifacts, and any interpretation or diagnosis must be made with reference to the original waveforms.
8. LVIS NeuroMatch EEG source localization visualizes brain electrical activity on a 3D idealized head model. LVIS NeuroMatch source localization additionally calculates and displays summary trends based on source localization findings over time.
9. This device does not provide any diagnostic conclusion about the patient's condition to the user.

Comparison of Intended Use and Technological Characteristics with the Predicate Devices:

Device	NeuroMatch (Proposed Device) LVIS	Epilog PreOp (Predicate Device) K172858	Curry Multimodal Neuroimaging Software (Reference Device) K001781	Rationale for Substantial Equivalence
Classification	21 CFR§882.1400, Electroencephalograph	21 CFR§882.1400, Electroencephalograph	21 CFR§882.1400, Electroencephalograph	Same classification as the Predicate device.
Product Code	OMB, OLT, OMA, OLX	OLX	OLX	Includes the same product code (OLX) as the Predicate and reference device. The additional product codes were based on the previous clearance of the NeuroMatch device under K241390.
Indications for Use For the subject device new indications are highlighted in bold while previous cleared indications are in normal font.	1. LVIS NeuroMatch Software is intended for the review, monitoring and analysis of electroencephalogram (EEG) recordings made by EEG devices using scalp electrodes and to aid neurologists in the assessment of EEG. The device is intended to be used by qualified medical practitioners who will exercise professional judgement in using the information.	PreOp is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects at least 3 years of age for the visualization of human brain function by fusing a variety of EEG information with rendered images of an individualized head model and an individualized MRI image.	The Neurosoft CURRY Multimodal Neuroimaging Software is intended for use by qualified/trained EEG technologists and/or physicians on both adult and pediatric subjects for the visualization and analysis of the electrical activity of the brain by fusing a variety of EEG and/or Magnetoencephalographic (MEG) data, with Magnetic Resonance (MRI), functional Magnetic Resonance (fMRI),	For the new source localization indication, the Proposed Device and the Predicate Device adopted similar language pertaining to the visualization of brain activity (EEG data) on a 3D display of the head. Although there are some differences in the phrasing of the indications for use, the differences do not constitute a new intended use. Both

Device	NeuroMatch (Proposed Device) LVIS	Epilog PreOp (Predicate Device) K172858	Curry Multimodal Neuroimaging Software (Reference Device) K001781	Rationale for Substantial Equivalence
	2. The Seizure Detection component of LVIS NeuroMatch is intended to mark previously acquired sections of adult EEG recordings from patients greater than or equal to 18 years old that may correspond to electrographic seizures, in order to assist qualified medical practitioners in the assessment of EEG traces. EEG recordings should be obtained with a full scalp montage according to the electrodes from the International Standard 10-20 placement. 3. The Spike Detection component of LVIS NeuroMatch is intended to mark previously acquired sections of adult EEG recordings from patients ≥ 18 years old that may correspond to spikes, in order to assist qualified medical practitioners		Computer Tomography (CT), Positron Emission Tomography (PET) and/or Single Photon Emission Computed Tomography (SPECT) images.	devices utilize software algorithms to visualize electrical activity of the brain for source localization.

Device	NeuroMatch (Proposed Device) LVIS	Epilog PreOp (Predicate Device) K172858	Curry Multimodal Neuroimaging Software (Reference Device) K001781	Rationale for Substantial Equivalence
	in the assessment of EEG traces. LVIS NeuroMatch Spike Detection performance has not been assessed for intracranial recordings. 4. LVIS NeuroMatch includes the calculation and display of a set of quantitative measures intended to monitor and analyze EEG waveforms. These include Artifact Strength, Asymmetry Spectrogram, Autocorrelation Spectrogram, and Fast Fourier Transform (FFT) Spectrogram. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms. 5. LVIS NeuroMatch displays physiological signals such as electrocardiogram (ECG/EKG) if it is provided in the EEG recording. 6. The aEEG functionality included in LVIS NeuroMatch			

Device	NeuroMatch (Proposed Device) LVIS	Epilog PreOp (Predicate Device) K172858	Curry Multimodal Neuroimaging Software (Reference Device) K001781	Rationale for Substantial Equivalence
	is intended to monitor the state of the brain. 7. LVIS NeuroMatch Artifact Reduction (AR) is intended to reduce muscle and eye movements, in EEG signals from the International Standard 10-20 placement. AR does not remove the entire artifact signal and is not effective for other types of artifacts. AR may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified medical practitioner trained in recognizing artifacts, and any interpretation or diagnosis must be made with reference to the original waveforms. 8. LVIS NeuroMatch EEG source localization visualizes brain electrical activity on a 3D idealized head model. LVIS NeuroMatch source localization additionally			

Device	NeuroMatch (Proposed Device) LVIS	Epilog PreOp (Predicate Device) K172858	Curry Multimodal Neuroimaging Software (Reference Device) K001781	Rationale for Substantial Equivalence
	calculates and displays summary trends based on source localization findings over time. 9. This device does not provide any diagnostic conclusion about the patient's condition to the user.			
Prescription/ Over-the-Counter	Rx	Rx	Rx	Same as the Predicate device.
Patient Population	Individuals ≥ 18 years undergoing EEG assessment	Adult and pediatric patients at least 3 years of age undergoing EEG assessment	Adults and pediatric patients undergoing EEG assessment	Similar: The Predicate Device is indicated for patients that are at least 3 years of age while the Proposed Device is limited to 18 yrs of age or older. The fact that the Proposed Device is not intended for younger pediatric patients does not change the intended use or raise new questions of safety and effectiveness. The age range for the Proposed Device is based on clinical validation data

Device	NeuroMatch (Proposed Device) LVIS	Epilog PreOp (Predicate Device) K172858	Curry Multimodal Neuroimaging Software (Reference Device) K001781	Rationale for Substantial Equivalence
				which spans the proposed target patient population.
Components	SaMD	SaMD	SaMD	Same as the Predicate device.
EEG Data Source	10-20 system	10-20 system	Up to 48 EEG channels (4kHz) • Up to 512 EEG channels (20kHz) ¹	Same as the Predicate device.
Source Localization				
Method of Display	Idealized head model	Individualized head model	Individualized head model Idealized head model	Differences in head models do not raise new questions of safety and effectiveness. LVIS has provided comparative testing between the Curry (reference device) and NeuroMatch device which demonstrates NeuroMatch's performance is non-inferior to that of the CURRY device when using an idealized head

¹ CURRY®, Signal Processing and Source Localization Multi-Modal Neuroimaging Suite, <https://www.compumedics.com.au/en/products/curry/>

Device	NeuroMatch (Proposed Device) LVIS	Epilog PreOp (Predicate Device) K172858	Curry Multimodal Neuroimaging Software (Reference Device) K001781	Rationale for Substantial Equivalence
				model. Comparative testing between the PreOp (predicate) device based on an individualized head model and the NeuroMatch also suggests that the performances of both devices are comparable.
Dipole Fit Required?	No	No	Yes	Same as the predicate device. Dipole fitting is not used by sLORETA; it is only necessary for some methods used by the Reference Device.
Source Estimation Methods	sLORETA	sLORETA	LORETA	Same as the predicate device. LVIS has provided comparative testing between the Curry (reference device based on the LORETA algorithm) and NeuroMatch device which demonstrates NeuroMatch's performance is non-inferior to that of the CURRY device. Comparative testing

Device	NeuroMatch (Proposed Device) LVIS	Epilog PreOp (Predicate Device) K172858	Curry Multimodal Neuroimaging Software (Reference Device) K001781	Rationale for Substantial Equivalence
				between the PreOp (predicate) device and NeuroMatch (both of which are based on sLORETA algorithm) also suggests that the performances of both devices are comparable.
Forward head models	Boundary Element Model (BEM)	Finite Difference Model (FDM)	• Sphere • Boundary Element Model (BEM) • Finite Difference Model (FDM)	The difference in forward head models does not raise different questions of safety or effectiveness. Head-to-head comparative testing between the Proposed Device and the predicate and reference devices demonstrates that device performance remains substantially equivalent despite these differences in technological characteristics.
Trends	Maximum Amplitude Projection Node Visit Frequency Node Transition Frequency	No Trends Provided	No Trends Provided	The difference of providing trends does not raise different questions of safety and effectiveness as these trends are mathematical

Device	NeuroMatch (Proposed Device) LVIS	Epilog PreOp (Predicate Device) K172858	Curry Multimodal Neuroimaging Software (Reference Device) K001781	Rationale for Substantial Equivalence
				operations on data that is presented to a user of previously cleared source localization devices. The trends were verified through performance testing.

Performance Data:

Non-clinical testing: Software Verification and Validation Testing for NeuroMatch indicates that the product meets predefined product's requirements.

The following performance data were provided to demonstrate safety and efficacy in support of substantial equivalence determination:

Source Localization:

Validation of NeuroMatch source localization (SL) algorithm was conducted over a test dataset collected from three independent and geographically diverse medical institutions; two located in the United States and one located in South Korea. The CURRY (K0001781) was chosen as a reference device for this validation study. To establish device performance, NeuroMatch SL algorithm was evaluated for non-inferiority against the reference device in a "head-to-head" comparison. Specifically, a clinical study was designed to evaluate the concordance of the SL algorithms and the resected brain areas, following the 510(k) summary of the FDA-cleared device PreOp (K172858). In this study, three US board-certified epileptologists were recruited to independently complete a survey. The physicians were presented with the source localization results of each device, along with normalized post-operative MRIs with distinctive resection regions. They were instructed to first determine the resection region at the sublobar level. They then assessed whether SL output of each device (NeuroMatch: sLORETA on idealized brain model, CURRY: LORETA on idealized brain model, PreOp: sLORETA on individualized brain model) had any overlap with the determined resection region at a sublobar level. For a particular patient, for every device, the physicians responded to a Yes/No question that asked whether there is concordance for the corresponding device. The data shows the NeuroMatch consistently demonstrated a higher number of acceptable SL outputs compared to CURRY. Further, NeuroMatch results demonstrated 39 out of 43 patients showing concordant results (4 discordant), compared to 37 out of 43 for CURRY (6 discordant). NeuroMatch demonstrated a success rate (number of patients with concordant results divided by the total number of patients) of 90.7% compared to 86% for CURRY. The lower bound of one-sided 95% CI of the success rate difference was -4.65%, which is greater than the pre-specified non-inferiority margin for this validation study and establishes that NeuroMatch is non-inferior to the reference CURRY device in the head-to-head comparison.

Dataset for clinical validation included patients 40% Male and 60% Female, and an Age range of 19-73 years old.

CURRY and NeuroMatch had a success rate of 81.3% and 87.5% in sixteen male patients, and a success rate of 88.9% and 92.6% in twenty seven female patients. This observation suggests there are no considerable gender-related differences in the device performance, and NeuroMatch SL is consistently non-inferior to CURRY. Results are shown in Table below.

Device success rate across genders		
Device	Gender	
	Male (N = 16)	Female (N = 27)
CURRY	81.3%	88.9%
NeuroMatch	87.5%	92.6%

Table: NeuroMatch SL performance remains consistent across genders and establishes a comparable performance to CURRY. Device success rates for CURRY and NeuroMatch across male and female patients.

LVIS divided the patients into four age groups to assess potential age-related effects on the device performances. These groups include intervals of [18-30), [30-40), [40-50), and 50 years old and above. Device performance for CURRY and NeuroMatch in each age group is shown in Table below. These results suggest that NeuroMatch SL performance is comparable to CURRY's performance consistently across age groups.

Device success rate across age				
Device	Age groups			
	[18, 30) (N = 11)	[30, 40) (N = 12)	[40, 50) (N = 14)	[50, 75) (N = 6)
CURRY	81.8%	91.7%	85.7%	83.3%
NeuroMatch	81.8%	91.7%	92.9%	100.0%

Table: NeuroMatch SL performance remains consistent across age groups and establishes a comparable performance to CURRY. Device success rates for CURRY and NeuroMatch across different age subgroups.

A similar study was also conducted comparing NeuroMatch to the predicate Epilog PreOp device. Results indicate that both devices have comparable performance establishing the substantial equivalence of NeuroMatch to the Predicate Device.

NeuroMatch and Epilog PreOp both demonstrate a success rate of 91.7% (95% CI: 79.16, 100).

Source Localization Trends:

Software verification and validation testing conducted by LVIS has shown that each trend calculation (Maximum Amplitude Projection, Node Visit Frequency, and Node Transition Frequency) has been implemented correctly. All of the test cases passed, confirming that the trends functioned as intended, performing the appropriate calculations and yielding the expected results on EEG datasets with known solutions. This validation process demonstrated the accuracy and reliability of the MAP, NVF, and NTF source localization trends. Furthermore, the clinical utility and interpretation of the trend was assessed

through a clinical survey of 15 clinicians. Clinicians were able to understand the function of each trend and provide information regarding the clinical utility of the trends in their workflow.

Summary:

The NeuroMatch device has the same intended use as the predicate device. In addition, it has similar technological characteristics; performance data demonstrates that any differences in technological characteristics do not raise different questions of safety or effectiveness. Therefore, the NeuroMatch device is substantially equivalent to the cleared predicate device.