November 26, 2024

LVIS Corporation
% Devjani Saha, PhD
Director, Neurology Regulatory Affairs
MCRA, Llc
803 7th St NW, 3rd Floor
Washington, District of Columbia 20001

Re: K241390
Trade/Device Name: NeuroMatch
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB, OLT, OMA
Dated: October 24, 2024
Received: October 25, 2024

Dear Devjani Saha:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241390

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. 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.

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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

Predicate Device:

Persyst 14, EEG Review and Analysis Software, K182181

Date Prepared:

November 25, 2024

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 18 years old or older. 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 K222450, with exception of the following additional features:

1. Spike detection;
2. Seizure detection;

Seizure and spike detection are substantially equivalent to the Persyst 14 device (K182181: Predicate). 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. Spike Detection

NeuroMatch Spike Detection identifies both spike waves and sharp waves. The NeuroMatch Spike Detection feature uses a deep learning-based algorithm that detects potential epileptiform spikes and annotates each detected potential spike with a unique identification. The detection of spikes in the EEG data is automatically triggered when an EEG file is uploaded by the user. The NeuroMatch Spike Detection feature identifies spikes and displays the spikes based upon the order (time) when the spike occurred.

2. Seizure Detection

The NeuroMatch Seizure Detection feature uses a deep learning-based algorithm to identify potential seizure events and annotates each detected potential seizure with a unique identification. Each annotation includes the start and end positions of the potential identified seizures.

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. 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:

TABLE 1: NEUROMATCH SUBSTANTIAL EQUIVALENCE TABLE

Device	**NeuroMatch (Proposed Device) K241390** LVIS	**Persyst 14 EEG Review and Analysis Software (Predicate Device) K182181** Persyst Development Corporation	**Rationale for Substantial Equivalence**
Classification	21 CFR§882.1400, Electroencephalograph	21 CFR§882.1400, Electroencephalograph	Same classification as the Predicate device.
Product Code	OMB, OLT, OMA	OMB, OLT, OMA	Same product code as the Predicate device.
Indications for Use: For the subject device new indications **are highlighted in bold** while previously 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 judgment 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,**	1. Persyst 14 EEG Review and Analysis Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (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 judgment in using the information. 2. The Seizure Detection component of Persyst 14 is intended to mark previously acquired sections of adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in	The Proposed Device and the Predicate, have similar Indications for Use. The Proposed Device's Indications for Use was developed to incorporate wording from the predicate device.

Device	NeuroMatch (Proposed Device) K241390 LVIS	Persyst 14 EEG Review and Analysis Software (Predicate Device) K182181 Persyst Development Corporation	Rationale for Substantial Equivalence
	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	the assessment of EEG traces. EEG recordings should be obtained with a full scalp montage according to the standard 10/20 system. 3. The Spike Detection component of Persyst 14 is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. The Spike Detection component is intended to be used in patients at least one month old. Persyst 14 Spike Detection performance has not been assessed for intracranial recordings. 4. Persyst 14 includes the calculation and display of a set of qualitative measures intended to monitor and analyze the EEG waveform. These include FFT, Rhythmicity, Peak Envelope, Artifact Intensity, Amplitude, Relative Symmetry and Suppression Ratio. Automatic event marking	

Device	NeuroMatch (Proposed Device) K241390 LVIS	Persyst 14 EEG Review and Analysis Software (Predicate Device) K182181 Persyst Development Corporation	Rationale for Substantial Equivalence
	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	is not applicable to the quantitative measures. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms. 5. Persyst 14 displays physiological signals, including the calculation and display of a heart rate measurement based on the ECG channel in the EEG recording, which are intended to aid in the analysis of an EEG. Heart rate measurement of Persyst 14 is not applicable to patients with pacemaker and/or active implantable devices. 6. The aEEG functionality included in Persyst 14 is intended to monitor the state of the brain. The automated event marking function of Persyst 14 is not applicable to aEEG. 7. Persyst 14 provides notifications for seizure detection, quantitative EEG and aEEG that can be used when processing a record during acquisition. These include an on screen display and the optional	

Device	NeuroMatch (Proposed Device) K241390 LVIS	Persyst 14 EEG Review and Analysis Software (Predicate Device) K182181 Persyst Development Corporation	Rationale for Substantial Equivalence
	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. This device does not provide any diagnostic conclusion about the patient's condition to the user.	sending of an email message. Delays of up to several minutes can occur between the beginning of a seizure and when the Persyst 14 notifications will be shown to a user. Persyst 14 notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert. 8. Persyst AR (Artifact Reduction) is intended to reduce EMG, eye movement, and electrode artifacts in a standard 10-20 EEG recording. 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 artifact, and any interpretation or diagnosis must be made with reference to the original waveforms. 9. This device does not provide any diagnostic conclusion about the	

Device		NeuroMatch (Proposed Device) K241390 LVIS	Persyst 14 EEG Review and Analysis Software (Predicate Device) K182181 Persyst Development Corporation	Rationale for Substantial Equivalence
			patient's condition to the user.	
Prescription/ Over-the-Counter		Rx	Rx	Same as the Predicate device.
Patient Population		Individuals ≥18 years undergoing EEG assessment	Adults and pediatric patients undergoing EEG assessment: - Seizure detection: Individuals ≥18 years - Spike detection at least one month old	Similar, the Proposed Device age group of at least 18 years old for seizure detection is the same as the predicate device. For spike detection, the subject device is intended for a subset of the population that is cleared for the predicate device.
Components		SaMD	SaMD	Same as the Predicate device.
EEG Data Source		10-20 system	10-20 system (spike and seizure detection)[1] up to 256 channels[2]	Similar, the Proposed Device and the Predicate both use 10-20 system.
EEG Functions	**Review, Monitor, and Analyze Recordings**	Yes	Yes	Same as the Predicate device.
	Annotation List	Yes	Yes	Same as the Predicate device.

[1] Persyst 14 User Manual, Persyst 14 Spike and Seizure Detection Description
[2] Persyst 14c Release Notes, Persyst EEG Electrical Source Imaging (ESI), https://www.persyst.com/support/persyst-release-notes/

Device		NeuroMatch (Proposed Device) K241390 LVIS	Persyst 14 EEG Review and Analysis Software (Predicate Device) K182181 Persyst Development Corporation	Rationale for Substantial Equivalence
	Measurements	**Previously Cleared:** • FFT Spectrogram • Artifact Strength • aEEG • Autocorrelation Spectrogram • Asymmetry Spectrogram **Added in Current 510(k):** • Seizure Detection • Spike Detection	• FFT • Artifact Intensity • Amplitude • Rhythmicity • Peak Envelope • Relative Symmetry • Suppression Ratio • Artifact intensity • FFT spectrogram • FFT power • FFT power ratio • FFT spectral edge • Relative asymmetry spectrogram • Absolute asymmetry index • Relative asymmetry index • aEEG • Rhythmicity spectrogram • Spike detection • Spike density • Seizure detection • Seizure probability • Spike Perception Score • VSBASLINE[3]	The Proposed Device and the Predicate both provide seizure and spike detection.
Seizure Detection		Yes, full montage	Yes, full montage	Same as the Predicate device.
Spike Detection		Yes	Yes	Same as the Predicate device.
Notifications		No	Yes, notifications for seizure detection, quantitative EEG, and aEEG.	This difference to the Predicate does not raise different questions of safety and effectiveness as the clinician should be

[3] Trending, https://www.persyst.com/technology/trending/

Device	NeuroMatch (Proposed Device) K241390 LVIS	Persyst 14 EEG Review and Analysis Software (Predicate Device) K182181 Persyst Development Corporation	Rationale for Substantial Equivalence
			reviewing and analyzing all data including the original EEG waveforms holistically.
Key: EEG = electroencephalography FFT= fast fourier transform ECG/EKG = electrocardiogram AR = artifact reduction aEEG = amplitude – integrated EEG 3D = 3 dimensional SaMD = software as a medical device			

Performance Data:

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

Non-Clinical Testing

- **Software verification and validation testing**

The following software verification and validation tests were completed per FDA's guidance entitled "Content of Premarket Submissions for Device Software Functions" issued June 2023:

  - Verification Tests and Regression Tests
  - Unit/Module Level and Integration Testing
  - Visualization Testing
  - Performance Testing

All tests successfully met their respective acceptance criteria and confirmed the software met its requirements and design.

- **Cybersecurity Testing**

A comprehensive battery of cybersecurity testing per FDA's guidance entitled "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (issued September 2023), including Configuration Assessment, Vulnerability Scanning, and Penetration Testing, was conducted.

- **Clinical Testing**

Seizure Detection Validation:

Clinical Sites:
Validation of the NeuroMatch seizure detection feature was conducted using EEG data collected in three independent and geographically diverse medical institutions.

Dataset Characteristics and subject demographics:
The demographics of seizure detection validation dataset are as follows:

	Patient *with at least 1* verified seizure event	Control *With 0* verified seizure event
Number of subjects	181	10
Total EEG hours (mean, median, [min, max])	979.40 (5.41, 6.0, [1.00, 8.00]	80 (8.00, 8.00, [8.00, 8.00]
Age, years (mean) (median and [min, max])	42.05 (39, [18, 89])	52.3 (60, [25, 78])
Gender (Male : Female)	95:86	4 : 6

Summary of Validation Testing
The following is a summary of the validation procedure performed:

- A validation dataset of EEG recordings obtained from adult (18 years and older) patients were utilized for validation testing. This dataset was completely separate and independent from the data used to design and train the algorithm.
- A reference standard was established for the validation dataset by a panel of three independent EEG trained neurologists who reviewed and annotated the EEG recordings for seizure episodes. Seizures were identified based on a 2 out of 3 majority rule.
- Both NeuroMatch and predicate Persyst 14 (K182181) Seizure Detection modules were run on the validation dataset and performance metrics were calculated for each as compared to the reference standard established per above.
- Statistical analysis was performed on the results to evaluate non-inferiority to the predicate device based on both sensitivity and false detection rate (FDR).
- Conducting an event-level analysis, with potentially an unlimited number of events per patient, introduces bias by disproportionately affecting the data distribution in favor of patients with many events. To avoid such bias, the study reports an event-level analysis with a capping value of six events per patient for seizure detection sensitivity.

Results:

	Sensitivity (N = 504 events)	**False Detection Rate (FDR)** (per 24 hrs)
Persyst 14	59.37 [56.94, 61.71]	4.26 [3.15, 7.39]
NeuroMatch	75.01 [72.62, 77.57]	3.74 [2.59, 5.44]

NeuroMatch and Persyst 14 sensitivity and false detection rate. Mean and 95% confidence intervals are shown.

Sensitivity: The acceptance criterion for non-inferiority required the upper limit of the 95% CI for the difference in sensitivity (Persyst 14- NeuroMatch) to be less than 10%. This criterion was met, confirming that NeuroMatch is non-inferior to Persyst 14.

FDR: The acceptance criterion for non-inferiority required the lower limit of the 95% CI for the difference in FDR (Persyst 14-NeuroMatch) to be greater than -4 per 24hr. This criterion was met, confirming that NeuroMatch is non-inferior to Persyst 14.

Conclusion:
NeuroMatch Seizure Detection passed non-inferiority testing to the Persyst14 (K182181), in both sensitivity and false-detection rate (FDR).

Spike Detection Validation:
Clinical Sites:
Validation of the NeuroMatch spike detection feature was conducted using EEG data collected in three independent and geographically diverse medical institutions.

Dataset Characteristics and Subject Demographics Summary Table:
The demographics of spike detection validation dataset are as follows:

	Patient *with at least 1* verified spike event
Number of subjects	149
Total EEG minutes (hours)	2752.72 (~45.9)
(mean, median, [min, max])	(18.47, 20 [10.0,0 20.00])
Age (mean) (median, [min, max])	42.56 (39, [18, 92])
Gender (Male : Female : Unspecified – Number of Subjects)	73 : 75 : 1

Summary of Validation Testing

The following is a summary of the validation procedure performed:

- A validation dataset of EEG recordings obtained from adult (18 years and older) patients were utilized for validation testing. This dataset was completely separate and independent from the data used to design and train the algorithm.
- A reference standard was established for the validation dataset by a panel of three independent EEG trained neurologists who reviewed and annotated the EEG recordings for spike events. The reference standard for spike is established with majority consensus among the annotating physicians (i.e., consensus of at least 2 out of the 3 physicians).
- Both NeuroMatch and predicate Persyst 14 (K182181) Spike Detection modules were run on the validation dataset and performance metrics were calculated for each as compared to the reference standard established per above.
- Statistical analysis was performed on the results to evaluate non-inferiority to the performance of the predicate device in terms of sensitivity and false detection rate.

Results:

	Sensitivity	**False Detection Rate (FDR) (per minute)**
Persyst 14	67.92 [61.96, 73.87]	3.61 [2.68, 4.53]
NeuroMatch	72.18 [66.81, 77.54]	3.24 [2.15, 4.33]

NeuroMatch and Persyst 14 sensitivity and false detection rate. Mean and 95% confidence intervals are shown.

Conclusion:

Sensitivity: The acceptance criterion for non-inferiority required the upper limit of the 95% CI for the difference in sensitivity (Persyst 14 - NeuroMatch) to be less than 15%. This criterion was met, confirming that NeuroMatch is non-inferior to Persyst 14.

FDR: The acceptance criterion for non-inferiority required the lower limit of the 95% CI for the difference in FDR (Persyst 14-NeuroMatch) to be greater than -1.5 per minute. This criterion was met, confirming that NeuroMatch is non-inferior to Persyst 14.

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.