December 22, 2020

Neurologic LLC
% Joshua Crist
Consultant
Biologics Consulting
1555 King Street
Alexandria, Virginia 22314

Re: K201910
Trade/Device Name: EZTrack
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT
Dated: November 19, 2020
Received: November 20, 2020

Dear Joshua Crist:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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)*
K201910

Device Name
EZTrack

Indications for Use *(Describe)*
EZTrack is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects with focal or multifocal epilepsy at least 3 years of age for the visualization of human brain function from analysis of electroencephalographic (EEG) signals produced by electrically active tissue of the brain. EZTrack calculates and displays the Fragility Index, a quantitative index based on an analysis of spatiotemporal EEG patterns that is intended for interpretation by trained physicians to aid in the evaluation of patients with focal or multifocal epilepsy.

The device does not provide any diagnostic conclusion about the patient's condition to the user and should be interpreted along with other clinical data, including the original EEG, medical imaging, and other standard neurological and neuropsychological assessments.

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

1. SUBMITTER

Submitter:	Neurologic LLC 6510 Chesterfield Avenue McLean, Virginia 22101 617-875-9380
Contact Person:	Sridevi Sarma President and Co-Founder Neurologic LLC 6510 Chesterfield Avenue McLean, Virginia 22101 617-875-9380
Submission Correspondent:	Joshua Crist Consultant Biologics Consulting 1555 King Street Alexandria, VA 22314 216-387-0199 jcrist@biologicsconsulting.com
Date Prepared:	November 13, 2020

2. DEVICE

Name of Device:	EZTrack
Common or Usual Name:	Electroencephalograph Software
Classification Name:	882.1400 - Electroencephalograph
Regulatory Class:	II
Product Code:	OLT

3. PREDICATE DEVICE

Predicate Device Name:	Persyst 14 EEG Review and Analysis Software

Manufacturer:	Persyst Development Corporation
510(k) Number:	K182181
Reference Devices:	GeoSource Electrical Geodesics, Inc. K092844

4. DEVICE DESCRIPTION

EZTrack is a web-based software-only device that allows visualization of human brain function based on the analysis of electroencephalographic (EEG) signals. The EZTrack algorithm produces a fragility score for each EEG recording node. The EZTrack fragility values are shown to correlate with regions that clinicians have annotated as seizure onset zones (SOZ) prior to resective surgery, and may be used in conjunction with other clinical data such as EEG, medial imaging, neuropsychological testing, and other neurologic assessments in order to aid in the evaluation of patients with focal or multifocal epilepsy. The device does not provide any diagnostic conclusion about the patient's condition. EZtrack displays the fragility of each EEG channel in a heatmap to aid in interpretation.

5. INDICATION FOR USE

EZTrack is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects with focal or multifocal epilepsy at least 3 years of age for the visualization of human brain function from analysis of electroencephalographic (EEG) signals produced by electrically active tissue of the brain. EZTrack calculates and displays the Fragility Index, a quantitative index based on an analysis of spatiotemporal EEG patterns that is intended for interpretation by trained physicians to aid in the evaluation of patients with focal or multifocal epilepsy.

The device does not provide any diagnostic conclusion about the patient's condition to the user and should be interpreted along with other clinical data, including the original EEG, medical imaging, and other standard neurological and neuropsychological assessments.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparison of Indications

The predicate device, Persyst 14 (K182181) has the following indications for use:

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 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 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 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 patient's condition to the user.

The predicate device has indications for use to output various quantitative and qualitative EEG marks, measurements, and indices. Similarly, EZTrack has indications for use to output and

display a novel, quantitative EEG index (the Fragility Index) that is intended to represent a measurement of node instability to aid in the evaluation of patients with focal epilepsy. Both devices analyze EEG data with software-only algorithms and display indices to the end user. EZTrack differs from the Persyst 14 indications for use in the specific analyses conducted, the display method, and in the target patient population (patients with focal or multi-focal epilepsy). These differences do not raise new types of safety and effectiveness questions and are supported by performance testing discussed below.

Comparison of Technology

EZTrack and the Persyst 14 (K182181) are both software-only devices that provide insights to the user about electrical activity in the brain. Both devices rely on algorithms that process raw EEG data in order to provide this information to the user. Neither device provides any diagnostic conclusion about the patient's condition to the user

The main technological differences between the two devices are the algorithms and resulting data visualization methods. The predicate Persyst 14 (K182181) performs a wide variety of calculations on EEG to provide various quantitative and qualitative EEG marks, measurements, and indices, such as seizure detection, spike detection, event marking, artifact reduction, and trends/qualitative measures. These data may be visualized with markups and notifications over EEG data, as well as various output visualizations for trends, such as FFT spectrogram, FFT power ratio, FFT spectral edge, relative asymmetry index, suppression ratio, spike density, and seizure probability trends.

EZTrack provides a different analysis than the predicate, i.e. a fragility analysis, which is a measure of node instability to evaluate whether the activity for each electrode is representative of epileptogenic activity. EZTrack can be used on scalp EEG, electrocorticography (ECoG), or stereoelectroencephalography (SEEG) data to aid in evaluation of patients with focal or multifocal epilepsy. EZTrack's resulting analyses are displayed in a heatmap.

EZTrack differs in the technological features of the algorithm and the method by which the results are displayed to the user. The differences in indications and technological features for EZTrack do not raise new types of safety and effectiveness questions. The same questions for each device include whether appropriate software verification and validation data have been provided to support the software, and whether clinical validation testing has confirmed the software meets the users' needs for the intended use of the device. This performance testing has been provided for EZTrack and therefore supports substantial equivalence of the proposed device to the predicate.

A comparison of technological features is provided in Table 1 below.

Table 1: Device Comparison Table

	Proposed Device	**Primary Predicate Device**	**Reference Device**
510(k) Number	TBD	K182181	K092844
Applicant	Neurologic LLC	Persyst Development Corporation	Electrical Geodesics, Inc.

	Proposed Device	Primary Predicate Device	Reference Device
Device Name	EZTrack	Persyst 14 EEG Review and Analysis Software	GeoSource
Classification Regulation	882.1400 Electroencephalograph	882.1400 Electroencephalograph	882.1400 Electroencephalograph
Product Code	OLT	OMB, OLT, OMA	OLX
Indications for Use	EZTrack is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects with focal or multifocal epilepsy at least 3 years of age for the visualization of human brain function from analysis of electroencephalographic (EEG) signals produced by electrically active tissue of the brain. EZTrack calculates and displays the Fragility Index, a quantitative index based on an analysis of spatiotemporal EEG patterns that is intended for interpretation by trained physicians to aid in the evaluation of patients with focal or multifocal epilepsy. The device does not provide any diagnostic conclusion about the patient's condition to the user and should be interpreted along with other clinical data, including the original EEG, medical imaging, and other standard neurological and neuropsychological assessments.	See Section 6 above.	GeoSource 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 idealized head model and an idealized MRI image
Software-Only	Yes	Yes	Yes
EEG Data Source	Any EEG, electrocorticography (ECoG), or stereoelectroencephalography (SEEG) data in European Data Format or Brain Vision format	Any EEG, electrocorticography (ECoG), or stereoelectroencephalography (SEEG) data.	Geodesic EEG System using Net Station
Methods of Calculation	Network Fragility Analysis	Various analyses, including seizure detection, spike detection, event marking, artifact reduction, and trends/qualitative measures.	Idealized Head Model (average) LORETA, LAURA, sLORETA

	Proposed Device	Primary Predicate Device	Reference Device
Method of Display	Fragility Heatmap	Markups and notifications over EEG data, as well as various output visualizations for trends, such as FFT spectrogram, FFT power ratio, FFT spectral edge, relative asymmetry index, suppression ratio, spike density, and seizure probability trend.	Idealized MRI (average)
Multiple Timepoints	As x-axis in heatmap	As x-axis in live monitoring or analyses	Frame-by-Frame
Computation Location	Performed on EZTrack Servers	Performed Locally on System, some remote analyses available	Performed Locally on System
Operating System	Web-Based Platform, accessible on Windows, Mac OS, Linux	Windows 10	Mac OS

7. DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

There are no direct or indirect patient-contacting components of the subject device. Therefore, patient contact information is not needed for this device.

Electrical Safety and electromagnetic compatibility (EMC)

Not applicable. The subject device is a software-only device. It contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a Moderate Level of Concern. This performance testing was also provided for the predicate, and this testing therefore supports substantial equivalence of the EZTrack device.

Bench Testing

Not Applicable. Bench testing was not necessary to establish the substantial equivalence of this device.

Animal Study

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Study

A retrospective study of 91 patients (462 seizures, 44 successes, 47 failures, ages 3-65) demonstrates that the EZTrack algorithm provides fragility data that correlates with the location of the clinically annotated Seizure Onset Zone (SOZ). Note this fragility data is used to aid in evaluation of patients with focal or multifocal epilepsy and does not provide any diagnostic conclusions about a patient's condition.

During invasive monitoring, clinicians attempted to identify visual EEG signatures (e.g. HFOs, spikes, or burst activity) to isolate the SOZ. Consensus agreement of the spatial distribution of visual EEG signatures together with pre-implantation data were used to construct the clinically annotated SOZ, which was an estimate of the true Epileptogenic Zone. The patients underwent a large resection, or targeted laser ablation, resulting in a resected region, which was generally a super set of the SOZ. Patients were categorized as either seizure free (success), or having seizure recurrence (failure) at their 6-12 months post-op evaluations.

EZTrack demonstrated a statistically significant difference (p-value=0.02) between the successful and failed Confidence Statistic distributions, and an average effect size difference between the two groups of 0.627. On average, fragility had a 0.627 higher standardized confidence in the clinically annotated SOZ in success outcomes, than in failed outcomes.

The Geodesics device (K092844) serves as a reference device to support the acceptability of these performance data collection methods. That is, both EZTrack and the reference device are supported by clinical data that demonstrate correlation of the algorithm output with the zone of tissue that physicians ultimately decide to resect, demonstrating the algorithms' validity as a source of information that may be used within then intended use of the respective devices.

The results of this study demonstrate that the EZTrack outputs a fragility index that can be used to aid in evaluation of patients with focal or multifocal epilepsy. Like the predicate device, clinical data has been provided for EZTrack to demonstrate the device meets the users' needs for the intended use of the device, therefore supporting substantial equivalence.

8. CONCLUSIONS

Both devices are software-only applications that provide algorithmic analyses of EEG data in order to provide insights into the electrical activity in the brain through indices displayed to the end user. The EZTrack device has different technological characteristics when compared to Persyst 14. EZ track differs in the way the EEG data are analyzed and in the way the data are displayed to the user. Neither device provides diagnostic conclusion about the patient's condition.

In summary, EZTrack has the same intended use as the predicate Persyst, has slight differences in the patient population and technological features, reflected in differences in the indications for use language. The differences in technological features/indications do not raise new questions of

safety and effectiveness and are supported by Software Verification/Validation Testing as well as Clinical Testing. The proposed EZTrack device is therefore substantially equivalent to the predicate Persyst 14 EEG Review and Analysis Software (K182181).