February 6, 2021

Brain Sentinel, Inc.
Richard Waite
Regulatory Consultant
8023 Vantage Drive Suite 216
San Antonio, Texas 78230

Re: K200276
Trade/Device Name: SPEAC System
Regulation Number: 21 CFR 882.1580
Regulation Name: Non-Electroencephalogram (EEG) Physiological Signal Based Seizure Monitoring System
Regulatory Class: Class II
Product Code: POS
Dated: January 22, 2021
Received: February 2, 2021

Dear Richard Waite:

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)*
K200276

Device Name
SPEAC System

Indications for Use *(Describe)*
The SPEAC® System is intended for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest.

The non-EEG Physiological Signal Based Seizure Monitoring System continuously records and stores surface electromyographic (sEMG) data for subsequent review.

Trained healthcare professionals may use the electrophysiological sEMG data during a post-hoc review, with other contextual data, to characterize upper-extremity motor activity (UEMA) ipsilateral to the device from other activity.

Audio data recorded during seizure monitoring may be available for review by a trained healthcare professional.

The device is to be used on the belly of the biceps muscle to analyze sEMG signals. When sEMG signal patterns associated with a unilateral, appendicular, tonic extension that could be associated with a GTC seizure are detected, the SPEAC System sends adjunctive alarms to alert caregivers.

Adjunctive alarms may be disabled by a physician order while continuing to record sEMG data for subsequent review.

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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K200276
Traditional 510(k) Summary

This 510(k) summary is prepared according to the elements outlined in 21 CFR 807.92 Content and format of a 510(k) summary.

Date Prepared February 05, 2020

Submitter Brain Sentinel, Inc
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(210) 951-8681

Contact Person Richard Waite, Sr.
(214) 662-9277
Richard_Waite@outlook.com

Subject Device K200276

Trade Name	SPEAC® System
Common Name	Physiological signal-based seizure monitoring system
Device Classification	Class II
Product Code & Regulation	POS; Non-EEG physiological signal-based seizure monitoring system; 21 CFR 882.1580
Review Panel	Neurodiagnostic Devices; Neurology

Predicate Device K182180

Manufacturer	Brain Sentinel, Inc.
Device Name	Brain Sentinel Monitoring and Alerting System
Regulation Name	Non-EEG physiological signal-based seizure monitoring system
Product Code	POS
Regulation Number	21 CFR 882.1580
Device Classification	Class II

Device Description

The SPEAC System is a wireless, non-invasive, physiological, surface electromyography (sEMG) recording, monitoring, and alerting system to be used as an adjunct to seizure monitoring during periods of rest. The System continuously records and stores surface electromyographic (sEMG) data for subsequent review by a physician. Trained healthcare professionals may use the electrophysiological sEMG data, with other contextual data, to characterize seizures with upper-extremity motor activity ipsilateral to the device from other

activity. SPEAC data gives healthcare professionals another diagnostic tool to characterize seizure events in a home or hospital setting.

The System continuously records and distributes sEMG data at 1,000 Hz (and audio around detected events) for post-hoc review by physicians (or other trained healthcare professionals) for the characterization of seizure events. A physician may perform post-hoc review of the SPEAC System data to characterize motor events that may be associated with seizures.

The seizure monitoring algorithm is able to send alarms to notify patients and caregivers when a pattern that may be associated with a generalized tonic-clonic (GTC) seizure is measured. Physicians may order the System with or without alarms and may order threshold adjustments to customize the level at which the System alarms.

Data collected by the System is uploaded to Brain Sentinel's secure remote storage, the Data Distribution System (DDS), and is remotely accessible for physician review. All patient data is cyber-secured within Microsoft Azure which is FedRAMP certified. Below, Tables 1 and 2 list the functional and operational outputs designed to provide feedback to the patient and caregiver. These modes and outputs are identical to those cleared in the predicate, K182180.

The SPEAC System remains the same with no alterations of any kind. The sEMG-based seizure monitoring algorithm is identical to the predicate SPEAC System. The purpose of this submission is to expand the indications for use based on clinical performance testing that was submitted to support a determination of substantial equivalence. When trained appropriately, clinicians may use the subject device to perform post-hoc analysis of the sEMG data from the device, with other contextual patient data, to characterize seizures with upper-extremity motor activity ipsilateral to the device from other activity.

Table 1: System Functional and Operational Outputs

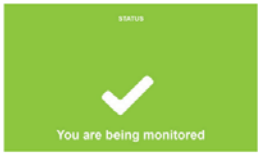
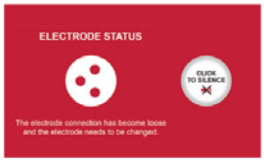
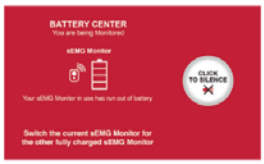
SPEAC® System Functional Mode	Left LED Light	Right LED Light	Daily Monitoring Application Screen View	Description of the Functional Mode
Seizure Monitoring Mode ON	Green Solid	Green Solid		Seizure Monitoring Mode: The patient is within the Wi-Fi covered area and being monitored for potential ES/NES/ PNES event. Seizure Alarms and Operational Alerts function in this mode.
Seizure Alarm Mode	Red Solid	Red Flash		If a Seizure Alarm condition has been received, the Seizure Alarm is automatically activated. Select the **CLICK TO SILENCE** button to silence the audible part of the alarm for a duration of five minutes. A new Seizure Alarm screen will appear asking, "Did the patient have a seizure?" Answer by clicking one answer: **YES, I Don't Know** or **NO.**
Record Only Mode Activated	Yellow Solid	Yellow Solid		Record Only Mode allows the patient to leave the Wi-Fi covered area while recording sEMG data for subsequent review by the referring physician. Seizure Alarms and Operational Alerts do not function in Record Only Mode.
Loose Electrode Alert	Yellow Flash	Red Flash		The Electrode Patch is not making good contact with the patient's arm and needs to be replaced. Follow the same steps for removing, replacing, and calibrating an Electrode Patch. Apply gentle pressure to the sEMG Monitor for two minutes to allow for electrode adherence to the patient's skin. If the issue persists, ensure all electrode snaps are properly fastened to the sEMG Monitor before adhering to the patient.
sEMG Monitor Critical Battery Alert	Blue Flash	Red Flash		The battery is critically low on the sEMG Monitor in use and must be connected to the Laptop Base Station for recharging. Swap the low battery sEMG Monitor with the sEMG Monitor that is fully charged. Follow the same steps for removing, replacing, and calibrating an Electrode Patch.
Laptop Base Station Critical Battery Alert	Green Solid	Green Solid		The battery is critically low on the Laptop Base Station and must be connected to the wall outlet for recharging. Ensure that the Base Station Laptop Power Supply (AC Mains) is connected to the wall outlet and that the Power Jack is connected to the Laptop Base Station.
Lost Connection Out of Wi-Fi Range Alert	Purple Solid	Red Flash		The sEMG Monitor in use is outside the covered range and has lost wireless connection with the SPEAC System. The patient should immediately return to a part of the house that is in the Wi-Fi covered zone. If the router is working properly, four blue glowing Signal Strength LEDs will be visible. If the LEDs are not lit, unplug and replug the router to the electrical wall outlet. Wait four minutes for the Wi-Fi connection to be restored.

Table 2: SPEAC System Outputs Intended for Patients and Caregivers

Name	Application View	Description
Settings Button		Click the **Settings button** to swap functional modes between Seizure Monitoring Mode and Record Only Mode.
Night Mode Button		To help the patient sleep soundly, the Laptop Base Station display screen and lights on the sEMG Monitor may be dimmed. Click the **Night Mode button** to turn Night Mode ON.
Night Mode On Button		Click the dark grey **Night Mode ON button** to disable Night Mode setting and return the SPEAC System display screen to regular brightness. You can alternate between Night Mode OFF and Night Mode ON as often as necessary.
Electrode Setup Button		Click the **Electrode Setup button** every time a new Electrode Patch is placed on a patient. Calibration of a new Electrode Patch should be performed daily when using the System in Seizure Monitoring Mode or Record Only Mode.
Alarm History Button		Click the **Alarm History button** to display a list of all Seizure Alarms and Operational Alerts that have occurred during the prescribed monitoring period. Use the scroll bar to review the cumulative list. A new or existing Seizure Diary entry can be accessed from this list, as well as using the Seizure Diary button noted below.
Seizure Diary Button		A yellow exclamation point will appear over the Seizure Diary button to indicate a new Seizure Diary entry has been automatically created. Click the **Seizure Diary Button** to open the electronic form that will allow the patient or caregiver to record specific details about the event.
Wi-Fi-Status Indicator Bar		The Laptop Base Station serves as the control hub for the entire SPEAC System. The Wireless Router provides a communications link between the sEMG Monitor in use and the Laptop Base Station. The Wireless Router can communicate with the sEMG Monitor up to a 200-foot range (approximate). The Wi-Fi Status Bars indicate connection signal strength.

Intended Use

The SPEAC® System is intended for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest. The non-EEG Physiological Signal Based Seizure Monitoring System continuously records and stores surface electromyographic (sEMG) data for subsequent review. Trained healthcare professionals may use the electrophysiological sEMG data during a post-hoc review, with other contextual data, to characterize upper-extremity motor activity ipsilateral to the device from other activity. Audio data recorded during seizure monitoring may be available for review by a trained healthcare professional.

The device is to be used on the belly of the biceps muscle to analyze sEMG signals. When sEMG signal patterns associated with a unilateral, appendicular, tonic extension that could be associated with a GTC seizure are detected, the SPEAC System sends adjunctive alarms to alert caregivers. Adjunctive alarms may be disabled by a physician order while continuing to record sEMG data for subsequent review.

Clinical Performance Testing

Prospective clinical trials entitled, "Using sEMG to Identify Epileptic Seizure Semiology" (Study 1), and "Differentiation of Epileptic and Psychogenic Non-Epileptic Seizures Using Single-Channel Surface Electromyography" (Study 2) evaluated the ability of trained clinicians to differentiate and characterize different types of seizure events using the sEMG data collected by the SPEAC System.

Once characterized, the results of these sEMG-trained healthcare professionals were compared to characterizations of the same seizure events using EEG data interpreted by epileptologists and compared to automated processing for characterization of the seizures.

Clinical Inclusion and Exclusion Criteria

Enrollment in the studies was limited to patients who met the following selection criteria: Patients with a history of epileptic seizures or psychogenic non epileptic seizures with positive motor involvement of the upper extremities admitted to the EMU for routine seizure characterization were eligible for inclusion. Subjects were not eligible if intracranial EEG monitoring was used.

Training of Physicians in the Study

Physicians were provided with a brief (less than an hour) sEMG data training session describing characteristics of: voluntary activity, epileptic and non-epileptic seizure events, and artifact from the device. False positives were non-seizure events that could have resulted from either voluntary movement, signal spikes or RF noise from loose electrodes, or ambient background signals with no associated event data. Physicians were asked to evaluate normalized, transformed, and raw sEMG data. Epileptologists reviewing sEMG data were blinded to all other data.

Clinical Endpoints. Trained clinicians were evaluated by determining if they could characterize and differentiate types of seizure events with sEMG data collected by the SPEAC System, and then those results were compared to vEEG data as well as automated event characterization.

Study Methods

Expert Review

Both Study 1 (CLN0055.001) and Study 2 (CLN0053.001) simultaneously captured vEEG and sEMG data, and three of the total four sEMG reviewers were the same in both studies. The goal in Study 1 was to review epileptic seizures and try to describe the semiology. The goal in Study 2 was to review both epileptic and non-epileptic seizures and to try to properly classify events into those two categories. The similarity between these studies is that epileptic seizures included GTC seizures (referred to as TC seizures in the studies), and focal seizures that contained clonic jerking and complex motor activity (automatisms). Tonic seizures were only recorded during Study 1, and PNES was only recorded during Study 2.

The data from the three common sEMG reviewers was combined from both studies to assess the accuracy for the intended goal in both studies. This analysis combines data that has two different goals but testing the same types of events. The combined accuracy for the studies given a "committee" style approach (majority rules, 2/3) was also analyzed to make the reviews more comparable to the format for used for vEEG.

Results

Expert Reviewer Accuracy

The accuracy from the three reviewers that participated in both studies was combined for each event. The accuracies are presented for each individual reviewer as well as a committee approach for each event. The objective of Study 1 was to categorize ES by semiology. The objective of Study 2 was to categorize seizures as epileptic or non-epileptic. The overall accuracy for individual assessments was 83% (95% CI [0.78 0.88], n = 243), and the overall accuracy for the committee approach was 86% (95% CI [0.77 0.93], n = 81). Table 1 summarizes the accuracies from the reviewers. These results support how the device can be used by clinicians to characterize upper-extremity motor activity (UEMA) ipsilateral to the device from other activity.

Table 1– Accuracy of (Common) Expert Reviewers' Classification of Events from Studies 1 and 2

Committee Review of sEMG Classification	Reviewer 1	Reviewer 2	Reviewer 3	Average (Ind. Assess.) (N = n*3) [a]	Committee
Tonic-Clonic (n = 26)	88% (95% CI [0.70 0.98])	88% (95% CI [0.70 0.98])	100% (95% CI [0.87 1.00])	92% (95% CI [0.84 0.97])	92% (95% CI [0.75 0.99])
Simple Motor ES (Tonic & Clonic, n = 14)	71% (95% CI [0.42 0.92])	79% (95% CI [0.49 0.95])	64% (95% CI [0.35 0.87])	71% (95% CI [0.55 0.84])	79% (95% CI [0.49 0.95])
Complex Motor ES ("Other", n = 22)	73% (95% CI [0.50 0.89])	68% (95% CI [0.45 0.86])	63% (95% CI [0.40 0.83])	68% (95% CI [0.56 0.79])	73% (95% CI [0.50 0.89])
All ES (n = 62)	79% (95% CI [0.67 0.88])	79% (95% CI [0.67 0.88])	79% (95% CI [0.67 0.88])	79% (95% CI [0.72 0.85])	82% (95% CI [0.70 0.91])
PNES, whole body involvement (n = 4)	100% (95% CI [0.40 1.00])	100% (95% CI [0.40 1.00])	100% (95% CI [0.74 1.00])	100% (95% CI [0.67 0.88])	100% (95% CI [0.40 1.00])
PNES, arm jerks/hand tremors only (n = 15)	100% (95% CI [0.78 1.00])	93% (95% CI [0.68 1.00])	93% (95% CI [0.68 1.00])	96% (95% CI [0.85 0.99])	100% (95% CI [0.78 1.00])
All PNES (n = 19)	100% (95% CI [0.82 1.00])	95% (95% CI [0.74 1.00])	95% (95% CI [0.74 1.00])	96% (95% CI [0.88 1.00])	100% (95% CI [0.82 1.00])
Overall Accuracy (n = 81)	**84% (95% CI [0.74 0.91])**	**83% (95% CI [0.73 0.90])**	**83% (95% CI [0.73 0.90])**	**83% (95% CI [0.78 0.88])**	**86% (95% CI [0.77 0.93])**

[a] – The sample size for this column is: TC: 78, Simple Motor ES: 42, Complex Motor ES: 66, All ES: 186, PNES whole body: 12, PNES arm jerks/hand tremors: 45, PNES: 57, Total: 243

The device used in the studies which represent the data collected were the same as the commercial version of the SPEAC System previously cleared by the FDA. sEMG collected using the SPEAC System has been used by clinicians to characterize seizures. Data provided by the SPEAC System provides healthcare professionals a diagnostic tool based on bicep sEMG signal monitoring to characterize seizure events measured in a home or hospital setting.

Non-clinical Test Summary

Test	Summary Results	FDA Recognition Number
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) (3rd Edition), Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	Passed	19-4
IEC 60601-1-2: 2014-02 (4th Edition), Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance, Collateral Standard, Electromagnetic Compatibility	Passed	19-8

Test	Summary Results	FDA Recognition Number
IEC 60601-1-6: Medical electrical equipment – Part 1-6: general requirements for basic safety and essential performance – collateral standard: usability	Passed	5-89
IEC 60601-1-8: Medical electrical equipment – Part 1-8: general requirements for basic safety and essential performance – collateral standard: general requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems	Passed	5-76
IEC 60601-1-11: 2010 (1st Edition) General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	Passed	This version is no longer FDA recognized but the changes evaluated in this 510(k) submission do not require additional testing to account for this lack of recognition. Changes to the subject device proposed (indications for use) are outside the scope of this test.
IEC 60601-2-40: 2016 (2nd Edition) Medical electrical equipment – Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment	Passed	N/A Not an FDA recognized standard; This testing has been voluntarily performed by the company to demonstrate performance and validate the system.
Biocompatibility Testing ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	Passed	2-220
ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for vitro cytotoxicity	Passed	2-245
ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Passed	2-174
Shipping and Distribution Test (ISTA 3A)	Passed	5-110
Software Verification and Validation (Appendix H)	Passed	N/A

SPEAC System Comparison to Predicate Device and Conclusion:

Parameter	SPEAC System	SPEAC System	Comparison
510(k)	**K200276**	**K182180**	
Indications for Use	The SPEAC® System is intended for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest. The non-EEG Physiological Signal Based Seizure Monitoring System continuously records and stores surface electromyographic (sEMG) data for subsequent review. Trained healthcare professionals may use the electrophysiological sEMG data during a post-hoc review, with other contextual data, to characterize upper-extremity motor activity (UEMA) ipsilateral to the device from other activity. Audio data recorded during seizure monitoring may be available for review by a trained healthcare professional. The device is to be used on the belly of the biceps muscle to analyze sEMG signals. When sEMG signal patterns associated with a unilateral, appendicular, tonic extension that could be associated with a GTC seizure are detected, the SPEAC System sends adjunctive alarms to alert caregivers. Adjunctive alarms may be disabled by a physician order while continuing to record sEMG data for subsequent review.	The SPEAC® System is indicated for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest. The System records and stores surface electromyographic (sEMG) data for subsequent review by a trained healthcare professional. The device is to be used on the belly of the biceps muscle to analyze sEMG signals that may be associated with generalized tonic-clonic (GTC) seizures. When sEMG signal patterns associated with a unilateral, appendicular, tonic extension that could be associated with a GTC seizure are detected, the SPEAC System sends adjunctive alarms to alert caregivers. Adjunctive alarms may be disabled by a physician order while continuing to record sEMG data for subsequent review.	Similar with new information added; The indications have been modified to clarify the intended use by specifically stating that the device may be used to characterize upper extremity motor activity by a trained healthcare professional. For clarification, Brain Sentinel removed “that may be associated with generalized tonic-clonic (GTC) seizures” in the second paragraph because the SPEAC System analyzes all sEMG to alarm for potential GTC seizures. These changes are supported by clinical performance testing included in the submission. All other claims were preciously cleared in K182180 (the predicate.

Parameter	SPEAC System	SPEAC System	Comparison
510(k)	**K200276**	**K182180**	
Classification	Class II 21 CFR 882.1580 Non-EEG physiological signal-based seizure monitoring system	Class II 21 CFR 882.1580 Non-EEG physiological signal-based seizure monitoring system	Same, No change
Product Code	POS	POS	Same, No change
Principle of Operation	sEMG signal, sampled at the rate of 1000 Hz, from the biceps brachii are processed by a proprietary algorithm to identify sustained sEMG contraction patterns—during the tonic phase and early transition to the clonic phase—that are pathognomonic of GTC seizures.	sEMG signal, sampled at the rate of 1000 Hz, from the biceps brachii are processed by a proprietary algorithm to identify sustained sEMG contraction patterns—during the tonic phase and early transition to the clonic phase—that are pathognomonic of GTC seizures.	Same, No change
Dimensions	3.44” x 2.34” x 1.33” (H x W x D)	3.44” x 2.34” x 1.33” (H x W x D)	Same, No change
Mass	127 g.	127 g.	Same, No change
Physical Controls	Power On/Off Button (Manual) Alarm Button Cancel Button	Power On/Off Button (Manual) Alarm Button Cancel Button	Same, No change
sEMG sampling rate	1,000 Hz	1,000 Hz	Same, No change
sEMG Frequency Bands of Interest	30-40 Hz, 130-240 Hz, and 300-400 Hz	30-40 Hz, 130-240 Hz, and 300-400 Hz	Same, No change
Event Monitored	Potential GTC Seizure	Potential GTC Seizure	Same, No change
Default Alarm Threshold	135	135	Same, No change
sEMG Monitor Power	Rechargeable Battery	Rechargeable Battery	Same, No change

Parameter	SPEAC System	SPEAC System	Comparison
510(k)	**K200276**	**K182180**	
Model	COTS Laptop	COTS Laptop	Same, No change
Input Power	115/230 VAC 50/60 Hz	115/230 VAC 50/60 Hz	Same, No change
Graphical User Interface	Laptop Base Station	Laptop Base Station	Same, No change
Software Controls	Alert Mode (adjunctive seizure detection and sEMG recording), Record Only (sEMG recording)	Alert Mode (adjunctive seizure detection and sEMG recording), Record Only (sEMG recording)	Same, No change
sEMG Electrode	sEMG Electrode	sEMG Electrode	Same, No change
Cellular Router	Cradlepoint Router	Cradlepoint Router	Same, No change
sEMG Monitor Recharging Accessories	USB – Micro-USB	USB – Micro-USB	Same, No change
Laptop Base Station Recharging Accessories	Medical-Grade Power Supply	Medical-Grade Power Supply	Same, No change
sEMG Monitor Arm Strap	Black Spandex Arm Strap	Black Spandex Arm Strap	Same, No change
Medical Device Data Systems	Physician Portal (SPEAC2ME®)	Physician Portal (SPEAC2ME®)	Same, No change

Limitations/ Warnings	• The System is available by prescription only from a physician or properly licensed practitioner. • The System should not be used as a standalone monitor for monitoring seizures and is not intended to be used during physical activity. • The device is not a seizure detection device. • The System alarms are not for standalone use and should not be used to guide medical therapy decisions. • The System has not been demonstrated to affect any clinical outcome such as status epilepticus, brain damage, or death following a GTC seizure. • The System does not predict sEMG signals that may be associated with GTC seizures. The device provides an alert from -30.82 – 25.06 seconds, with an average of 5.34 seconds (SEM ± 2.86), following the onset of sEMG activity that may be associated with a GTC seizure. • The System does not predict seizure onset. • The safety and effectiveness of the System has not been established in pediatric populations. • The System has not been tested in the home environment. • The safety and effectiveness of the SPEAC System has not	Same as subject device	Same, No change

Parameter	SPEAC System	SPEAC System	Comparison
510(k)	K200276	K182180	
	been established in monitoring sEMG signals that may be associated with seizures other than the GTC seizure. • The sEMG Electrode Patch may result in skin irritation that may lead to hypersensitivity in some individuals. • Never allow the sEMG Monitor to be submerged in any liquid. Contact Brain Sentinel if the sEMG Monitor or Laptop Base Station has been submerged. Do not attempt to use or service a sEMG Monitor or Base Station that has been submerged. • Only Brain Sentinel authorized equipment should be used with or connected to the SPEAC System. • The Laptop Base Station is optimized for the functions performed by the SPEAC System. Do not install applications, uninstall applications, or alter the configuration or environment variables of this.		

Conclusion

The SPEAC System remains the same with no alterations of any kind. The sEMG-based seizure monitoring algorithm is identical to the predicate SPEAC System. The purpose of this submission is to expand the indications for use based on clinical performance testing that was submitted to support a determination of substantial equivalence. When trained appropriately, clinicians may use the subject device to perform post-hoc analysis of the sEMG data from the device, with other contextual patient data, to characterize seizures with upper-extremity motor activity ipsilateral to the device from other activity. Based on device characteristics, indications for use, and testing submitted to support the submission, the SPEAC® System is substantially

equivalent to the predicate device, K182180, SPEAC System. No automated processing for seizure characterization was cleared in this 510(k).