September 27, 2024

Brain Electrophysiology Laboratory Company, LLC
Phan Luu
Chief Scientist
1776 Millrace Drive
Suite 304
Eugene, Oregon 97403

Re: K241513
Trade/Device Name: Sourcerer
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLX
Dated: August 28, 2024
Received: August 28, 2024

Dear Dr. Luu:

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

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)*
K241513

Device Name
Sourcerer

Indications for Use *(Describe)*
The software is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects at least 16 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.

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

1. SUBMITTER	
Submitter Name: Address: Phone Number: Contact Person: Date Prepared:	Brain Electrophysiology Laboratory Company, LLC 1776 Millrace Drive, Eugene, OR 97403 541-653-9797 Dr. Phan Luu June 10 2024
2. DEVICE	
Device Trade Name: Common Name: Classification Name, Number & Product Code: Class: Classification Panel:	Sourcerer Electroencephalograph Software Electroencephalograph 21 CFR 882.1400 OLX II Neurology
3. PREDICATE DEVICES	
Primary Predicate Device: Intended use:	K092844 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.
The primary predicate device has not been subject to a design-related recall.	

4. DEVICE DESCRIPTION

Sourcerer is an EEG source localization software that uses EEG and MRI-derived information to estimate and visualize cortex projections of human brain activity. Sourcerer is designed in a client-server model wherein the server components integrate directly with FLOW - BEL's software. Inverse source projections are computed on the server using EEG and MRI data from FLOW using the Electro-magnetic Inverse Module (EMIM API). The inverse results are interactively visualized in the Chrome browser running on the client computer using the Electro-magnetic Functional Anatomy Viewer (EMFAV). A functional overview and high-level communication pattern are shown in Figure 1. EMFAV is hosted on

FLOW's web server, from which the client computer can make requests when opening an MFF file using Sourcerer.

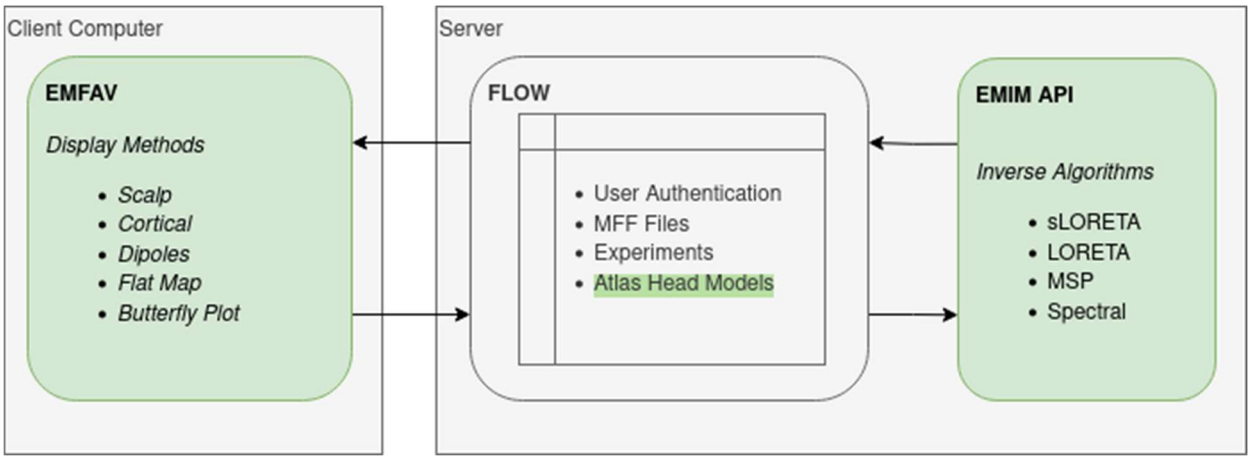

Figure 1. Architecture Overview of Sourcerer. Sourcerer is divided into three software components shown in green: EMFAV, EMIM API, and Atlas Head Models.

5. INDICATIONS FOR USE

The software is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects at least 16 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

	New Device	*Primary Predicate Device*
Device name	Sourcerer	GeoSource
510(k) number		K092844
Manufacturer	*Brain Electrophysiology Laboratory Company LLC*	EGI
Regulation	882.1400	882.1400
Product Code	OLX	OLX
Device Classification Name	Class II	Class II
Software only product	Yes	Yes

Computer OS	MS-windows 7, Mac OS, Linux. *Is cloud based and relies on web browser for user interface.*	Mac OS
MRI visualization	Idealized MRI (average)	Idealized MRI (average)
Source estimation methods: Linear inverse methods	LORETA, sLORETA, Multiple Sparse Priors—MSP	sLORETA,LORETA, LAURA
Forward head modeling	Finite Element Method (FEM). Tissues and respective conductivities (S/m) include: air = 0.0 CSF = 1.6 eyes = 1.55 skull = 0.006 scalp = 0.3, gray matter = 0.45 white matter = 0.2	Sphere, Finite Difference Model (FDM). Tissues and respective conductivities (S/m) include: air = 0.0 CSF = 1.79 eyes = 1.55 skull = 0.01 scalp = 0.33 gray matter = 0.25 white matter = 0.35

Table 1: Comparison of the new device to the predicate device

Summary of Technological Characteristics	Inputs: Sourcerer takes as inputs hdEEG data. Electrical Head Models*:* Sourcerer uses idealized (i.e., atlas) head models to describe current flow from cortex to scalp, where the EEG is recorded. Conductivity values: Sourcerer use different conductivity values for each of the different head tissues. Forward model: Sourcerer uses the Finite Element Method (FEM) to derive forward model. Inverse Methods: Sourcerer uses the LORETA, sLORETA and Multiple Sparse Priors (MSP) inverse methods. Display: Sourcerer displays the results on idealized head models
Substantial Equivalence Comparison	The identified equivalent device is GeoSource K092844. GeoSource is equivalent and different to Sourcerer in the following ways: • Like GeoSource, Sourcerer takes as inputs hdEEG data. • Electrical Head Models: Like Sourcerer, GeoSource uses idealized (i.e., atlas) head models to describe current flow from cortex to scalp, where the EEG is recorded. Atlas head models for both Sourcerer and Geosource characterize the

same brain tissues: scalp, skull, eyeballs, air, cerebral spinal fluid, gray matter and white matter.

- Sourcerer and GeoSource use different conductivity values for each of the different head tissues (detailed below).
- Another difference between Sourcerer and GeoSource atlas head models is the way in which the forward model (i.e., how current flow is modeled) is computed. Sourcerer uses the Finite Element Method (FEM) whereas GeoSource uses the Finite Difference Method (FDM) and spherical model (which is not relevant for the present evaluation).
- Inverse Methods: Like Sourcerer, GeoSource uses the LORETA and sLORETA inverse methods. However, Sourcerer includes an additional inverse method (Multiple Sparse Priors—MSP) not supported by GeoSource.
- Display: Like Sourcerer, GeoSource displays the results on idealized head models.

7. PERFORMANCE DATA

Algorithmic testing of HexaFEM and Inverse methods

HexaFEM

HexaFEM is the computational modeling method used to compute current flow from a position on the cortex through the various head tissues in the Sourcerer device.

Comparison of a three-layer sphere between HexaFEM and Spherical Analytics showed that the HexaFEM solutions are consistent with the analytical solutions for the three-layer spherical model.

HexaFEM and FDM Results

Similar to the three-layer sphere analytics, we compared the HexaFEM and FDM solutions for one realistic head model using the same conductivity values. Results showed that the HexaFEM and the FDM solutions are the same.

Inverse Model (EMIM Module)

The inverse solvers were tested using test files with known signal sources. The known signals are from the forward projection, using an atlas head model, of current from each dipole to the scalp. The scalp data from the forward projections signals, with no noise added per standard procedure from scientific literature, were then used to recover the source generator (known) with the various inverse solvers.

	Results are quantified as localization error distance (i.e., distance of the source estimate from the original source generating the scalp signal). LORETA: The average localization error is about 7 mm. The localization error distance is similar to what is reported for LORETA from the creator of LORETA. sLORETA Source estimation results are exact for the simulated signal sources. This fully replicates the simulated results reported by the creator of sLORETA. MSP The results show 100% (zero localization error), as expected.
Clinical Performance Testing	The clinical data used in the evaluation is obtained from epileptic patients during standard presurgical evaluation. The data from the clinical assessment used in the current clinical evaluation are hdEEG (256 channels) data, resected region (from MRI) and clinical outcome. The hdEEG data allow for Electrical Source Imaging (ESI) to be performed, the resected region provides an anatomic location to compare the ESI results, and the clinical outcome provides assurance that the resected location can be trusted as a ground-truth location. ESI was performed on an average inter-ictal spike derived from each patient's pre-operative hdEEG recording in both Sourcerer and Geosource. For each patient, the Euclidian distance between the location of maximal amplitude and the nearest voxel of the resected boundary was calculated for both devices. Performance of Sourcerer was shown to be equivalent to GeoSource.
Software Verification and Validation Testing	Validation testing involved algorithm testing which validated the accuracy of Sourcerer. The product was deemed fit for clinical use. Sourcerer was designed and developed as recommended by FDA's Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device". According to AAMI/ANSI/IEC 62304 Standard, Sourcerer safety classification has been set to Class B. "Basic Documentation Level" applied to this device.

8. CONCLUSION

The information discussed above and provided in the 510(k) submission demonstrate that the Sourcerer device is substantially equivalent to the predicate.