January 8, 2018

Epilog
% Patsy Trisler
Consultant
Qserve Group US Inc.
5600 Wisconsin Avenue
Chevy Chase, Maryland 20815

Re: K172858
Trade/Device Name: PreOp
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLX
Dated: October 4, 2017
Received: October 10, 2017

Dear Ms. Trisler:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172858

Device Name
PreOp

Indications for Use *(Describe)*
PreOp is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects at least 3 years of age for the visualization of human brain function by fusing a variety of EEG information with rendered images of an individualized head model and an individualized MRI image.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

1. SUBMITTER

Submitter Name: Epilog

Submitter Address: Vlasgaardstraat 52
9000 Gent, Belgium

Phone Number: +32484777651

Contact Person: Gregor Strobbe

Date Prepared: 18 September 2017; updated 18 December 2017

2. DEVICE

Device Trade Name: PreOp

Common Name: Electroencephalograph Software

Classification Name, Number & Product Code: Electroencephalograph
21 CFR 882.1400
OLX
Class: II
Classification Panel: Neurology

3. PREDICATE DEVICES

Primary Predicate Device: K092844, GeoSource
Intended use: 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.

Secondary Predicate Device: K001781, Curry Multimodal Imaging Software
Intended use: No 510(k) Summary Posted; not publicly available.

The secondary predicate device has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

PreOp is medical device software that combines EEG data and MR images to visualize recorded EEG activity in 3D in the brain. In figure 5.1 we present a general overview of the PreOp device. PreOp can be subdivided in 3 main modules: 3D Electrical Source Imaging (i.e. 3D ESI), Report generation and Viewer generation. The device's input is the MRI and EEG data that are uploaded by the user to the PreOp cloud environment. The output of the device is a report containing the results of the visualization and the ability to evaluate the results in 3D using the 3D viewer. The user can access the output through the PreOp cloud environment.

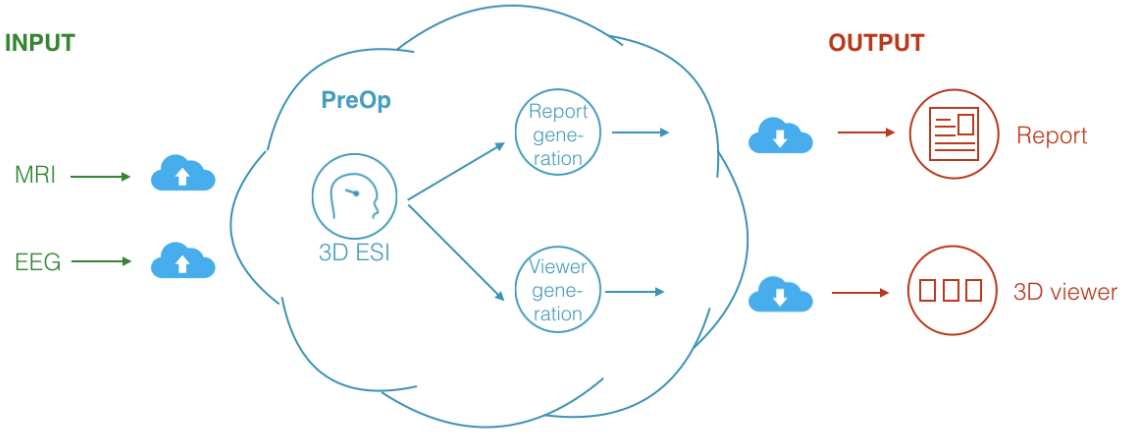

Figure 5.1: General overview of PreOp

5. INDICATIONS FOR USE

PreOp is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects at least 3 years of age for the visualization of human brain function by fusing a variety of EEG information with rendered images of an individualized head model and an individualized MRI image.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

	New Device	Primary Predicate Device	Secondary Predicate Device
Device name	PreOp	GeoSource	Curry multimodal neuroimaging software
510(k) number		K092844	K001781
Manufacturer	Epilog	EGI	Neurosoft Inc.
Regulation	882.1400	882.140	882.1400
Device Classification Name	Class II	Class II	Class II
Software only product	Yes	Yes	Yes
Computer OS	MS-windows 7	Mac OS	MS-windows 7

MRI visualization	Individualized MRI	Idealized MRI (average)	Idealized MRI (average) and individualized MRI
Source estimation methods: • Dipole fit • Linear inverse methods	No sLORETA	Yes sLORETA, LORETA, LAURA	Yes LORETA
Forward head modeling	Finite Difference Model (FDM)	Sphere, Finite Difference Model (FDM)	Sphere, Boundary Element Model (BEM), Finite Element Model (FEM)

Table 5.1: Comparison of new device to predicate device

Summary of Technological Characteristics

The intended use are the same, and the technological characteristics are essentially the same, as those of the predicate, K092844, GeoSource.

The PreOp device has two different modeling features that the predicate does not have.
First, the predicate device only works with idealized anatomical MR images. The usage of idealized anatomical MR images is however a special case of the more generic modeling framework of PreOp. If an idealized MRI is given to PreOp, an equivalent forward model will be constructed as in GeoSource (see section 20.1 for a comparison). The use of individualized anatomical MR images is implemented as described in the Secondary Predicate Device, K001781. There is no essential difference in technological characteristics between PreOp and the K001781 device since the Finite Element Model is equivalent to the Finite Difference Model from an individualized forward modeling point of view.
Second, a segmentation of CSF, white matter tissue and air has been added. The use of additional tissues does not raise different questions of safety and effectiveness. See *Neuroimage: Clinical 5(2014) 77-83*, which concludes that the PreOp modeling of CSF, white matter and air in addition to 3-compartment, scalp, skull and gray matter of the predicate device is substantially equivalent for clinically accurate ESI.

Substantial Equivalence Comparison

Both the The PreOp and the predicate have the same intended use. Both devices enable visualization of human brain function by fusing a variety of EEG information with MRI image.

From the standpoint of both functionality and workflow The PreOp device is substantially equivalent to the identified predicate as follows:

- Within The PreOp and its predicate, the user can provide EEG input data.
- The PreOp and its predicate are designed to segment EEG

activity and visualize EEG activity in 3D in the brain using an MR image.

- The PreOp and its predicate use externally acquired medical data and user input to achieve the result.
- The intended patient population is > 3 years in both devices.
- Both devices use the standard 10/20 positioning system of the electrodes and work with a distributed dipole source space.
- Both devices use the finite difference method for forward modeling and sLORETA as linear inverse source estimation method.

Verification tests were written and executed to ensure that the system is working as designed. The PreOp passed testing and was determined safe and effective for its intended use.

Performance testing data for PreOp is available in the relevant sections of the 510(k) document to support the Substantial Equivalence determination.

7. PERFORMANCE DATA

Non-Clinical testing	Validation and Verification Testing carried out on the PreOp indicates that it meets its predefined product's requirements and requirements from the following product standard: • AAMI/ANSI/IEC 62304:2006, Medical Device Software – Software Life Cycle Processes
Clinical Performance Testing – study 1	In order to compare the source localization performance of PreOp as compared to that of the predicate device, a retrospective data analysis of 18 epilepsy subjects aged 3 to 55 who had previously undergone resection surgery was provided. The analysis compared the source localization accuracy of the PreOp software algorithms (i.e., sLORETA with the finite difference model [FDM] using an individualized anatomical MRI) to that of the predicate algorithm (i.e., sLORETA with the finite difference model [FDM] using a idealized anatomical MRI). All subjects had previously undergone a long-term EEG registration prior to resection surgery, had operative data available that described the resected zone, and were determined to be Engel I postoperatively. The study included subjects with temporal and extratemporal resected zones. Each subject's EEG was automatically processed using the FDA approved spike detection algorithm of Persyst and spikes were then grouped according to topographic distribution and then averaged relative to the peak of the spike to increase the signal-to-noise ratio. The average of the most dominant group was used in the source estimate. The time point used in the source estimate was the peak of the spike. The data were

	then run through the PreOp software algorithms and the predicate algorithm. Three experienced epileptologists were provided the source localization results along with summaries of the postoperative reports and asked to rate whether each of the algorithm solutions (sLORETA with the finite difference model [FDM] using an idealized or individualized anatomical MRI) were concordant on a sublobular level. The results demonstrated that the proposed PreOp algorithms were substantially equivalent to the predicate device algorithm.
Clinical Performance Testing – study 2	In this study the performance was compared of spike source localization using HD-EEG recordings (128 or 256 electrodes) and Low Density LD-EEG recordings (25 electrodes). By evaluating the source localization results, we found that both algorithms provided identical source locations in 13 epileptic spikes using LD-EEG and HD-EEG recordings in 8 patients. Only in 3 spikes the spike localization was not 100% equivalent but very close to each other.
Software Verification and Validation Testing	Validation testing involved algorithm testing which validated the accuracy of PreOp. The product was deemed fit for clinical use. Usability validation is part of the Clinical Performance data and PreOp was tested and meets the requirements of following standard: • AAMI/ANSI/IEC 62366:2007, Medical devices – Application of usability engineering to medical devices. PreOp was designed and developed as recommended by FDA's Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device". PreOp was considered to represent "moderate" level of concern as it is not intended to provide recommendations for treatment nor to provide decisive information. According to AAMI/ANSI/IEC 62304 Standard, PreOp safety classification has been set to **Class B.**

8. CONCLUSION

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