February 13, 2026

Clouds of Care
Gregor Strobbe
CEO
Kliniekstraat 27a
Ghent, 9050
Belgium

Re: K252565
Trade/Device Name: PreOp v3
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLX
Dated: January 14, 2026
Received: January 14, 2026

Dear Gregor Strobbe:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252565

Device Name
PreOp V3

Indications for Use *(Describe)*
PreOp V3 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.

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510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92.

1 General information

Date prepared	13 August 2025	
Company	Clouds of Care Kliniekstraat 27a Gent 9050 BELGIUM	
Primary Contact Person	Nick de la Croix Head of Compliance Email: nick.delacroix@cloudsofcare.com Phone: +32 494 23 81 53	
Device	Trade Name	PreOp V3
	Common Name	Electroencephalograph software
	Classification Name (Regulation)	Source Localization Software for Electroencephalography or magnetoencephalography
	Classification Number	882.1400
	Classification Panel	Neurology
	Device Class	Class II
	Primary Product Code	OLX
Predicate Device	Trade Name	PreOp
	Common Name	Electroencephalograph software
	Company	Epilog
	510(k) clearance	K172858
	Classification Name (Regulation)	Source Localization Software for Electroencephalography or magnetoencephalography
	Classification Number	882.1400
	Classification Panel	Neurology
	Device Class	Class II
	Product Code	OLX
Device description	PreOp is medical device software that combines EEG data and MRI images to visualize recorded EEG activity in 3D in the brain. 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 provided by means of Persyst software. 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 Persyst software.	

Intended Use / Indications for Use	PreOp V3 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.

2 Technological characteristics

2.1 Technological similarities between subject PreOp and the predicate PreOp V1

The following table provides a detailed overview of the technological similarities between the subject PreOp and the predicate PreOp.

Features	Subject PreOp V3	Predicate PreOp K172858
Indications for Use	PreOp V3 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.	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.
Software only product	Yes	Yes
Computer OS	SaaS product in AWS infrastructure	SaaS product in AWS infrastructure
Source estimation methods	sLORETA	sLORETA
Forward head modeling	Finite difference Model (FDM)	Finite difference Model (FDM)
Prescription / over the counter	Prescription	Prescription

2.2 Technological differences between subject PreOp and the predicate PreOp V1

The subject device, PreOp V3, incorporates technological enhancements compared to the predicate device PreOp V1 (K172858) while maintaining the same intended use, patient population, and core functional principles. PreOp V3 includes integration with the Persyst EEG Review and Analysis Software, allowing clinical users to access PreOp functionality directly within the Persyst interface, whereas PreOp V1 required operators to access the system through a separate cloud-based workflow. PreOp V3 also standardizes the anatomical workflow by supporting both an idealized (average) MRI model and individualized, patient-specific MRI data, whereas PreOp V1 supported only individualized MRI. PreOp V3 automates multiple functions that were previously performed manually in the

predicate device, including EEG data preprocessing, spike detection, MRI segmentation, and clustering, thereby improving workflow efficiency without altering user control of final review steps. The spike clustering algorithms in PreOp V3 is enhanced to incorporate morphology and topography-based features, supporting improved precision of spike classification.
PreOp V3 also introduces a modernized, modular, containerized software architecture that replaces the monolithic design of PreOp V1. This updated architecture uses cloud-native microservices, enabling improved scalability, maintainability, and system performance, particularly when handling larger datasets. Additionally, PreOp V3 includes 3D visualization capabilities for head models and electrode positioning, improved temporal and spatial accuracy of source estimation, and refined reporting features with automated quality control checks.
These updates represent workflow, architectural, and performance improvements but do not change the intended use, fundamental technology, or overall operational principles of the device.

2.3 Summary of non-clinical performance data

2.3.1 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's 2023 guidance, "Content of Premarket Submissions for Device Software Functions."

PreOp was tested in accordance with IEC 62304:2006 + A1:2015: Medical device software – Software life-cycle processes (FDA Recognition Number: 13-79).
All required verification and validation activities have been completed to support the safety and performance of the software.

2.3.2 Summary of Clinical Performance Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of PreOp.

3 CONCLUSION

The information discussed above and provided in the 510(k) submission demonstrate that PreOp V3 is substantially equivalent to the predicate.