March 12, 2025

QuantalX Neuroscience
% Bosmat Friedman-Cox
Regulatory Consultant
ProMedoss, Inc.
6026 Beech Cove Ln.
Charlotte, North Carolina 28269

Re: K243746
Trade/Device Name: Delphi Amplifier
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL
Dated: December 5, 2024
Received: February 14, 2025

Dear Bosmat Friedman-Cox:

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,

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)*
K243746

Device Name
Delphi Amplifier

Indications for Use *(Describe)*
The Delphi Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG signals and to transmit them digitally to a computer. The device is intended for use on humans. The device is intended for use in a clinical environment (e.g., hospital, physician's office, etc.). The device is not intended for use in life support systems.

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 [Traditional 510(k)]
Delphi Amplifier - K243746

1 SUBMITTER

Applicant's Name:
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Date Prepared: February 14, 2025

Trade Name:
Delphi Amplifier

Classification Code:
Device: Amplifier, Physiological Signal
Product Code: GWL
Regulation No: 882.1835
Class: 2
Review Panel: Neurology

2 PREDICATE DEVICE

Primary Predicate:

- eego amplifiers. Product code: GWL, cleared under: K172312.

3 DEVICE DESCRIPTION

The Delphi Amplifier has been designed as a mobile recording device for EEG (electroencephalography) signals. It provides access to recorded data over a USB connection to external software over its signal driver interface. The Delphi Amplifier is powered via a USB connection and does not require any additional power source. The Delphi Amplifier supports EEG acquisition and storage by Referential DC input channels, and Parallel trigger input channels.
The Delphi Amplifier enables connection of up to 48 referential channels and 8bit trigger input channel. Impedance values can be measured for all referential electrodes as well as the reference. An SDK (Software Development Kit) is available for direct amplifier communication.

The device is powered by the USB port connection to a computer. The USB port supports interface to the computer running the SDK.

4 INDICATIONS FOR USE

The Delphi Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG signals and to transmit them digitally to a computer. The device is intended for use on humans. The device is intended for use in a clinical environment (e.g., hospital, physician's office, etc.). The device is not intended for use in life support systems.

5 SUBSTANTIAL EQUIVALENCE

The Delphi Amplifier is substantially equivalent to the predicate device based on the following:

6 INTENDED USE

The intended use of the proposed device is the same as that of the cleared device.

7 TECHNOLOGY

The Delphi Amplifier device has similar overall technological characteristics as the predicate eego amplifier cleared under K172312. Both devices are comprised of an amplifier unit provided with the Software Development Kit (SDK) and accompanying user manuals for both components. Both devices are prescription devices intended to be used in a clinical environment by connecting to a PC and FDA cleared electrodes to acquire EEG signals.

Attribute	**Subject Device** ***Delphi Amplifier***	**Predicate Device** ***Eego Amplifier***	**Comparison**
510(k) Number	NA	K172312	--
Classification	GWL	GWL	Same
Regulation Number	882.1835	882. 1835	Same
Intended Use	Used to electrically amplify signals derived from electroencephalogram	Used to electrically amplify signals derived from electroencephalogram.	Same
Indications for use	The Delphi Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG signals and to transmit them digitally to a computer. The device is intended for use on humans. The device is intended for use in a clinical environment (e.g., hospital, physician's office, etc.). The device is not intended for use in life support systems.	The eego amplifier is intended to be used by or under the direction of a physician for acquisition of EEG signals and to transmit them digitally to a computer. The device is intended for use on humans. The device is intended for use in a clinical environment (e.g., hospital, physician's office, etc). The device is not intended for use in life support systems.	Same
Type of use	Prescription Use	Prescription Use	Same
Modes of Operation	Connected to a PC and FDA cleared electrodes to acquire EEG signals	Connected to a PC and FDA cleared electrodes to acquire EEG signals	Same
Use Environment	Clinical environment (hospital, clinic, physician's office, etc.)	Clinical environment (hospital, clinic, physician's office, etc.)	Same
Filter	Low pass filtering in amplifier	Low pass filtering in amplifier	Same
Sampling rate	125, 250, 500, 1000, 2000 Hz @ all channels 5000 Hz @ 24 EEG monopolar or	EE-2XX Series: Up to 16384 Hz Set through the user interface of the Software Development	Equivalent; Delphi Amplifier can be configured to higher

Attribute	Subject Device *Delphi Amplifier*	Predicate Device *Eego Amplifier*	Comparison
	bipolar channels 10000 Hz @ 16 EEG monopolar or bipolar channels 50000 Hz @ 4 EEG monopolar or bipolar channels set through SDK	Kit (SDK) software EE-4XX Series: Up to 2048 Hz	sampling rate in reduced montage.
Amplifier CMRR (referential)	>100 dB	>100 dB	Same
Amplifier Input Channels	Up to 48	Up to 64	Similar; while Delphi has less input channels, there are various FDA cleared devices with 16-128 input channels.
Amplifier input impedance (referential)	$>10^8$ Ohm	$>10^9$ Ohm	Equivalent for low impedance of physiological signal inputs.
Amplifier power	USB from Computer	EE-2XX Series: Rechargeable integrated battery EE-4XX Series: USB from Computer	Same as EE-4xx model
Resolution and input stage	24-bit, true DC input for all channels	24-bit, true DC input for all channels, one A/D converter per channel	Similar
Input noise (referential)	< 0.9 uV p-p (lowest sampling rate and signal range)	<1.0 µVRMS (lowest sampling rate and signal range)	Equivalent
Amplifier referential DC input channels	Yes	Yes	Equivalent
Amplifier trigger input	Yes	Yes	Equivalent
Amplifier trigger input channel	Yes	Yes	Equivalent
Amplifier USB interface	Yes	Yes	Equivalent
PC interface	SDK (API)	SDK (API)	Equivalent

8 DISCUSSION

Based on the comparison presented in our submission, the Delphi Amplifier shares the same indications for use as its predicate, as both are intended for intended to be used by or under the direction of a physician for acquisition of EEG signals and to transmit them digitally to a computer. Additionally, while some technological differences do exist between the subject device and its predicate, testing have demonstrated that the device is substantially equivalent to its predicate and that the technological differences do not raise new safety and effectiveness concerns and support the company's substantial equivalency claim.

9 PERFORMANCE DATA

The Amplifier underwent successful nonclinical bench tests to establish substantially equivalent performance. The tests are summarized below:

Test	Test Method Summary	Results
Particular requirements for the basic safety and essential performance of electroencephalographs	Per IEC 80601-2-26 and IEC 60601-2-26	Pass
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Per IEC 60601-1	Pass
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	Per IEC 60601-1-6	Pass
Medical electrical equipment: Part 1-2 General requirements for basic safety and essential performance. Collateral Standard: electromagnetic disturbances- Requirements and tests.	Per IEC 60601-1-2, 60601-2-26 and IEC TR 60601-4-2	Pass
System Design Requirement	Stress test assessing data packet loss over 24 hours as well as long term registration test over 24 hours	No errors encountered. Test passed
Reliability testing	Multiple units tested for reliability over 3160 hours of continuous use. Quality checks performed every 24 hours and main characteristics checked every 1000 hours.	Pass
Delphi amplifier software and firmware testing	Software and firmware testing to ensure device operates per specifications.	Pass
System performance testing	Supplemental testing to IEC 80601-2-26 which included Common-mode rejection ratio, Noise Test and Impedance test	Pass

The results of the bench testing support the safety profile of the device and demonstrate that the device functions as intended.

10 CONCLUSION

The Delphi Amplifier has similar intended use, technological characteristics, and principles of operation as the predicate. Any differences between the subject and predicate device were evaluated through design verification and validation testing which demonstrated device performance and safety, and do not raise any new questions of safety and effectiveness. Based on the information submitted in this 510(k), the Delphi Amplifier is substantially equivalent to the predicate eego Amplifiers.