February 6, 2025

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

Re: K243243
Trade/Device Name: Delphi MCS Electrode Cap
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 11, 2024
Received: January 17, 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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Physical Medicine 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243243

Device Name

Delphi MCS Electrode Cap

Indications for Use *(Describe)*

Delphi MCS Electrode Cap is an EEG electrode set intended for routine clinical settings where rapid placement of large number of EEG electrodes is desired.

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.

510(k) Summary
K243243

Date Prepared: January 17, 2025

1 SUBMITTER

Applicant's Name:
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Israel

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Device:
Trade/Device Name: Delphi MCS Electrode Cap
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY

2 PREDICATE DEVICE

Primary Predicate:
Manufacturer: Electro-Cap International Inc
Trade name: Electro-Cap System
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Product code: GXY
510(k) number: K112319

3 DEVICE DESCRIPTION

The Delphi MCS Electrode Cap is made of elastic textile material, preserving the shape and size. The cap provides the exact position of the electrodes on the head without the need for additional measurements and adjustments. Large holes are provided for ventilation and access to the electrodes and patient's skin. The cap is fixed to the head with a chinstrap.
The Cap is available in the following sizes: XL 60-66cm, XL/L 57-63cm, L 54-60cm, L/M 51-57cm, M 48-54cm. The textile caps sizes are identifiable by the color material or seam and marking according to international system 10-20.
The Ag/AgCl electrodes are designed to provide minimal polarization and long-term stability of the signal.

The conductive surface of the electrodes which is housed inside the electrode base does not have direct skin contact; an electrically conductive substance (hydrogel) is used inside the electrode base for improved conductivity.
Delphi Cap electrodes are thin cup Ag/AgCl sintered electrode for EEG recording. The electrodes are designed for maximum comfort while the patient in a supine position. The design of this electrode is suitable for conducting combined TMS-EEG studies. The Ag/AgCl sintered electrode material guarantees minimum polarization and long-term signal stability, as well as an increased electrode life.

4 INDICATIONS FOR USE

Delphi MCS Electrode Cap is an EEG electrode set intended for routine clinical settings where rapid placement of large number of EEG electrodes is desired.

5 SUBSTANTIAL EQUIVALENCE

The Delphi MCS Electrode Cap is substantially equivalent to the predicate device based on the following:

5.1 Intended Use

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

5.2 Technology

The Delphi MCS Electrode Cap has similar overall technological characteristics as the predicate
Electro-Cap System (K112319). Both devices are comprised of an elastic fabric cap which allows for the connection of multiple electrodes via plastic electrode mounts incorporated in the cap. In both devices, electrode placement follows International 10-20 System of Electrode Placement. Both devices include Ag/AgCl electrode sensors and transmit electrophysiological signals from the patient to data collection devices with maximum impedance of 5 kΩ.
The Delphi MCS Electrode Cap is available in the following sizes: XL (60-66cm), XL/L (57-63cm), L(54-60cm), L/M (51-57cm), and M (48-54cm). The various sizes are color coded per international standards. The cap is provided with electrodes, connectors, ear clips and a chinstrap.

Attribute	**Subject Device**	**Predicate Device**	**Comparison**
	Delphi MCS Electrode Cap	***Electro-Cap System***	
510(k) Number	TBD	K112319	--
Classification	GXY	GXY	Same
Regulation Number	882.132	882.132	Same
Indications for use	Delphi MCS Electrode Cap is an EEG electrode set intended for routine clinical settings where rapid placement of large number of EEG electrodes is desired.	The Electro-Cap System is intended for use in routine clinical and research settings where rapid placement of a number of EEG electrodes is desired.	Same

Attribute	Subject Device *Delphi MCS Electrode Cap*	Predicate Device *Electro-Cap System*	Comparison
Target population	Adults	Adults, children, newborns, babies (infants)	Subject device includes only sizes relevant to adults and teenagers; equivalent
Intended user	Trained Technician, Neurologist	Trained Technician, Neurologist	Same as predicate
Environment of use	Electrophysiological	Electrophysiological	Same as predicate
Patient position	Sitting or reclining or supine position	Sitting or reclining or supine position	Same as predicate
Contact duration	Short-term	Short-term	Same as predicate
Number of electrodes (excluding ear electrodes)	Up to 32	Up to 256	Subject device has less electrodes but is within the range of the predicate; equivalent
EEG leads Scheme	10-20	10-20, 10-10, 10-5	Substantially Equivalent
Size of caps	Various sizes available (M to XL)	Various sizes available (babies to adult sizes)	Similar; subject device caps fall within the range of predicate sizes
Style of Caps	Full Head Cap with chinstrap or chest belt, ear slits	Full Head Cap with chinstrap or chest-belt, ear slits	Same as predicate
Cap material	Textile material (neoprene)	Textile material (spandex)	Similar; both devices underwent biocompatibility tests
Electrode mounts	Plastic (polyurethane)	Plastic (polyethylene)	Similar; both devices underwent biocompatibility tests
Location of wiring	Outside cap	Inside cap	Different; wire location does not introduce new safety or effectiveness concerns
Cable length	Various – 1.2 m to 1.8 m	Various – 0.9 m to 1.5 m (3 to 5 feet)	Similar; length difference does not introduce new safety or effectiveness concerns
Type of cable	Standard ribbon cable or/and lead wires or/and shielded lead wires	Standard ribbon cable or/and lead wires or/and shielded lead wires	Same
Type of electrode drop	Detachable	Detachable and non-detachable	Substantially Equivalent
Electrode sensor material	Ag/AgCl	Pure Tin, Ag, Ag/AgCl, Gold	Similar to predicate; both devices underwent biocompatibility tests
Type of connectors	D-sub connectors, KEL connector, Touchproof Din sockets and special connectors to match EEG equipment	D-sub connectors, Touchproof Din sockets and special connectors to match EEG equipment	Same
Method of connection to amplifier	Directly (if scheme is compatible) or through a special cable/adapter	Directly (if scheme is compatible) or through a special cable/adapter	Same
Performance requirements	Needs to transmit electrophysiological signals from an individual to data collection devices	Needs to transmit electrophysiological signals from an individual to data	Similar to predicate

Attribute	Subject Device *Delphi MCS Electrode Cap*	Predicate Device *Electro-Cap System*	Comparison
	with maximum impedance of 5 kΩ and parameters. Does not transmit electrical current, nor are they intended to be used for stimulation	collection devices with maximum impedance of 5 kΩ and parameters. Does not transmit electrical current, nor are they intended to be used for stimulation	
Reusability	Reusable	Reusable	Same
Conductive gel	Use only with FDA cleared gel	Use only with FDA cleared gel	Same
Sterile	No	No	Same

6 DISCUSSION

Based on the comparison presented in our submission, the Delphi MCS Electrode Cap shares the same indications for use as its predicate, as both are intended for rapid placement of a large number of EEG electrodes. 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.

7 PERFORMANCE DATA

The Delphi MCS Electrode Cap underwent successful nonclinical bench tests to establish substantially equivalent performance. Performance tests included:

- Biocompatibility:
  - Cytotoxicity per ISO 10993-5:2009
  - Sensitization per ISO 10993-10:2021
  - Irritation per ISO 10993-23:2021
- Electrical safety per IEC 60601-1
- Use cycle reliability and durability testing (resistance, noise, impedance, durability and repeated cleaning cycles)
- AC Impedance
- Offset Voltage
- Combined offset instability and internal noise
- Bias current tolerance
- Shelf Life
- Conductive connection compliance

The biocompatibility evaluation was conducted within the risk management framework and in compliance with ISO 10993 standards. This evaluation of the device included relevant data sources related to biological safety of finished device testing, and component material history of safe biological use and testing. This biocompatibility evaluation establishes the biological safety for the Delphi MCS Electrode Cap.

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

8 CONCLUSION

The Delphi CMS Electrode Cap 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 MCS Electrode Cap is substantially equivalent to the predicate Electro-Cap System.