August 20, 2025

QuantalX Neuroscience Ltd.
% Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: DEN250002
Trade/Device Name: Delphi-MD System
Regulation Number: 21 CFR 882.1860
Regulation Name: Non-invasive Evoked Response Brain Stimulator
Regulatory Class: Class II
Product Code: SFN
Dated: January 3, 2025
Received: January 3, 2025

Dear Kelliann Payne:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Delphi-MD System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Delphi-MD System is intended to elicit, amplify, record, and display brain evoked potentials to transcranial magnetic stimulation (TEPs) of the left and right primary motor cortex, dorsolateral prefrontal cortex, and primary visual cortex. The device is also intended to analyze TEPs and provide quantitative output parameters of the evoked response including the TEP waveform, global mean field potential, local mean field potential distribution maps, quantify amplitudes and latencies of the response, and present the output parameters compared to a normative reference database. The normative reference database age range is limited to 50-75 years of age.
>
> The Delphi-MD System is not to be relied on solely to make or confirm a diagnosis.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Delphi-MD System, and substantially equivalent devices of this generic type, into class II under the generic name non-invasive evoked response brain stimulator.

FDA identifies this generic type of device as:

> **Non-invasive evoked response brain stimulator**. A non-invasive evoked response brain stimulator is a device used to apply a stimulus to the brain, without direct contact with the brain, for the purpose

of measuring the evoked brain activity response. This device type is not intended as a standalone diagnostic for any condition.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On January 3, 2025, FDA received your De Novo requesting classification of the Delphi-MD System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Delphi-MD System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Delphi-MD System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation
Inaccurate stimulation and/or inaccurate brain activity measurement leading to: • Misinterpretation of results • Delayed diagnosis and/or patient treatment • Inappropriate or incorrect patient treatment	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Electromagnetic compatibility (EMC) testing Labeling
Device malfunction leading to injury of user/patient (e.g., shock, burn, interference)	Non-clinical performance testing Electrical, mechanical, and thermal safety testing Software verification, validation, and hazard analysis Electromagnetic compatibility (EMC) testing Labeling

In combination with the general controls of the FD&C Act, the non-invasive evoked response brain stimulator is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated

conditions for use and include the following:

(i) Evaluation of the device output and clinical interpretation, including repeatability and reliability of the device data outputs;

(ii) Description of the construction of the normative database, including the following:

(A) How the clinical work-up was completed to establish a normative population, including the establishment of inclusion and exclusion criteria; and

(B) Statistical methods and model assumptions used; and

(iii) Evaluation of the safety and performance of the stimulus, including mechanism of delivery and associated stimulation parameters.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and evaluate the performance of the methods utilized to elicit and measure the evoked brain activity response.

(3) The tissue-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance testing must demonstrate electrical safety, thermal safety, mechanical safety, electromagnetic compatibility (EMC), and wireless coexistence of the device in the intended use environment.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include the following:

(i) A detailed description of the device technical parameters, such as stimulation parameters;

(ii) An explanation of all device data outputs;

(iii) Conditions of use that may impact the accuracy, reliability, or functionality of the device measurement and operation;

(iv) Conditions that may preclude use of the device, such as implanted medical devices or medical conditions;

(v) A statement that the device is not a standalone diagnostic device and does not replace clinical decision making; and

(vi) A description of the normative database population and resulting parameters.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the non-invasive evoked response brain stimulator they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Kevin Khuu at 240-402-1662.

Sincerely,

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For David McMullen, M.D.
Director
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health