November 5, 2024

QuantalX Neuroscience
℅ Bosmat Friedman
Regulatory Consultant
ProMedoss, Inc.
6026 Beech Cove Lane
Charlotte, North Carolina 28269

Re: K242345
Trade/Device Name: Delphi Stimulator
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: August 5, 2024
Received: August 7, 2024

Dear Bosmat Friedman:

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,

Jay R. Gupta -S

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)*
K242345

Device Name
Delphi Stimulator

Indications for Use *(Describe)*
The Delphi Stimulator is intended to be used for stimulation of peripheral nerves for diagnostic purposes.

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 Stimulator
510(k) Number K242345

1 SUBMITTER

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Date Prepared: August 1, 2024

2 DEVICE

Trade Name:
Delphi Stimulator

Classification Code:	**Device:** Stimulator, Electrical, Evoked Response **Product Code:** GWF **Regulation No:** 21 CFR 882.1870 **Class:** 2 **Review Panel:** Neurology

3 PREDICATE DEVICE

Primary Predicate:

- MagPro, Model R20, by Tonica Elektronik A/S. Product code: GWF, cleared under: K160280.

4 DEVICE DESCRIPTION

Delphi stimulator is a Magnetic stimulator used for Magnetic stimulation of peripheral nerves for diagnostic purposes. Magnetic stimulation is a non-invasive technique for stimulating neural tissue. Application areas of magnetic stimulation are a sub-set of the application areas for current stimulation. The Delphi stimulator is connected to a Magnetic Coil which transfers the magnetic stimulation to the tissue.

The stimulator consists of power electronics to generate the magnetic field in the Magnetic Coil. It is controlled via a user interface installed on a PC workstation connected to the stimulator. enabling the operator to overview all functions, stimulus sequences, controls, status and measured data. The magnetic pulse is Biphasic waveform and the stimulator can stimulate with a frequency of up to 3 pulses per second (pps).

5 Indications for Use

The Delphi Stimulator is intended to be used for stimulation of peripheral nerves for diagnostic purposes.

6 Substantial Equivalence

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

7 Intended Use

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

8 Technology

The Delphi Stimulator device has similar overall technological characteristics as the predicate MagPro R20 (K160280). Both devices are comprised of a stimulator box and an attached probe. The stimulator box of both devices consists of power electronics circuitry which enables the action of accumulating energy in high voltage capacitor bank and discharge it rapidly on the probe load creating stimulation magnetic energy. Both devices have the same biphasic output stimulation shape and a very similar pulse width. Overall, the devices are very similar, however, the maximal available Delphi Stimulator output parameters are slightly lower than those of the predicate (per design). A comparative assessment between the Delphi Stimulator and predicate was conducted demonstrating that 100% amplitude of the Delphi stimulator is identical to 83% amplitude of the predicate device, and both have the same biphasic pulse duration. With respect to magnetic field parameters, the Peak Magnetic field strength at 2 cm [Tesla] at stimulators maximum output is 0.374 T for Delphi and 0.45 T for the predicate which correspond to 83% of predicate device which still provides the appropriate range for peripheral nerve stimulation for majority of cases with the likelihood of reduced occurrence of adverse events.

Attribute	**Subject Device** ***Delphi Stimulator***	**Predicate Device** ***MagPro R20 + MC-B65HO-2m*** **Tonica Elektronik A/S**	Comparison
510(k) Number	NA	K160280	--
Classification	GWF	GWF	Same
Regulation Number	882.1870	882.1870	Same
Indications for use	The Delphi Stimulator is intended to be used for stimulation of peripheral nerves for diagnostic purposes.	MagPro R20 is intended to be used for stimulation of peripheral nerves for diagnostic purposes.	Same
Probe (coil)			
Probe configuration	Figure-8 coil shape	Figure-8 coil shape	Same
Probe core material	Air core	Air core	Same
Probe dimensions	Inner diameter: 26.3mm Outer diameter: 60mm Winding height: 5.3mm Number of windings: $2\times(2\times13)$	Inner diameter: 35mm Outer diameter: 75mm Winding height: 11mm Number of windings: $2\times(2\times5)$	Similar; the dimensions of the Delphi Probe are slightly smaller; the probe and stimulator as a system produce the same magnetic stimulation up to 83% of predicate amplitude.
Output Stimulation Parameters			

Attribute	Subject Device *Delphi Stimulator*	Predicate Device *MagPro R20 + MC-B65HO-2m* **Tonica Elektronik A/S**	Comparison
Amplitude	[0 – 1.42] SMT	[0 – 1.7] SMT	Delphi amplitude is slightly lower than the predicate.
Output stimulation shape	Biphasic	Biphasic	Same
Pulse width	285 µsec	280 µsec	Same
Pulse per second	3 pps	20 pps	Delphi maximal pps is lower than the predicate.
Maximum coil current at coil SMT	5260A peak @ 1.42 SMT	6630A peak @ 1.7 SMT	Delphi result is lower than the predicate
Magnetic Field			
Peak Magnetic field strength at 2 cm [Tesla] at stimulators maximum output	0.374 T	0.45 T	Delphi peak magnetic field strength is slightly lower than the predicate.
Peak dB/dt at 2 cm [Tesla/ µsec] at stimulators maximum output	0.0081	0.01	Delphi result is lower than the predicate
Peak dB/dt at coil surface [Tesla/ µsec] at stimulators maximum output	0.0067	0.016	Delphi result is lower than the predicate
General			
Input power	Power Supply: 110V – 240V, 50/60 Hz Power consumption: Maximum 1200VA No isolation transformer	Power Supply via Isolation Transformer Power Supply: 120V~, 50/60 Hz. Power consumption: Maximum 800VA	Different; electrical safety demonstrated per IEC 60601-1
Mechanical data	Dimensions (HxWxD): 210 x 440 x 500mm Weight: 20 kg	Dimensions (HxWxD): 150 x 390 x 440mm Weight: 20 kg	Similar; Delphi is larger than the predicate and has the same weight
Console	Delphi consists of a power module and a processor control module	MagPro R20 consists of a power module, a processor module and built in displays.	Similar, however, Delphi Stimulator does not have a built-in display.
User Interface	User interface located on a PC and displays: • Intensity display (%) • Coil temperature Menu display and indicators can show: • Repetition rate • Pulses in train • Number of trains • Inter train interval • System mode (inactive/active)	MagPro R20 has 2 displays • Intensity display • Coil temperature Menu display and indicators can show: • Repetition rate • Pulses in train • Number of trains • Inter train interval • Start delay • Volume • Status: enable/disable	Similar; Delphi provides user control over stimulation output.

9 DISCUSSION

Based on the comparison presented in our submission, the Delphi Stimulator shares the same indications for use as its predicate, as both are intended to be used for stimulation of peripheral nerves for diagnostic purposes. Additionally, while some technological differences do exist between the Delphi Stimulator and its predicate, comprehensive 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.

10 Performance Data

The Delphi Stimulator underwent successful nonclinical bench tests to establish substantially equivalent performance including EMC and electrical safety per IEC 60601-1 and IEC 60601-1-2, demonstration of compliance with IEC 60601-4-2, software validation, performance bench testing as well as comparative testing. The results of the bench testing support the safety profile of the device and demonstrate that the device functions as intended.

Test	Test Method Summary	Results
Stimulator Output Comparison to Predicate	Stimulation output was measured in SMT units (Electrical field) and compared to the predicate (per FDA Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems)	The obtained results demonstrated substantial equivalency
System verification testing	The device was operated at various intensities to verify it functions as intended	No failures were observed; test passed.
ASCA test for basic safety and essential performance	Testing per IEC 60601-1 and IEC 60601-1-2	Pass
Software testing	Software testing per the requirement of the software life cycle as defined in IEC 62304:2006 Amendment 2015 - Medical device software - Software life cycle processes.	Pass
Cybersecurity assessment	Evaluation of threat per: - FDA Guidance, Post-market Management of Cybersecurity in Medical Devices - FDA Guidance, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. - AAMI TIR57:2016Principles for Medical Device Security-Risk Management - FDA Guidance, Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act	No vulnerabilities were found; labeling includes all required elements addressing cybersecurity

11 Conclusion

The Delphi Stimulator 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 and comparative 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 Stimulator is substantially equivalent to the currently marketed predicate MagPro R20.