DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 31, 2017

Tonica Elektronik A/S
Lise Terkelsen
QA/RA Manager
Lucernemarken 15
Farum, 3520 DK

Re: K162873
Trade/Device Name: MEP Monitor
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: February 27, 2017
Received: March 1, 2017

Dear Lise Terkelsen:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162873

Device Name
MEP Monitor

Indications for Use *(Describe)*
The MEP Monitor is an accessory for the MagPro stimulators (MagPro R30, MagPro R30 including MagOption, MagPro X100, and MagPro X100 including MagOption) and is intended to monitor evoked potentials.

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.

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510(k) Summary

Submitter's Information

Name of 510(k) owner:	Tonica Elektronik A/S Lucernemarken 15 DK-3520 Farum, Denmark
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Contact person:	Lise Terkelsen

Preparation date:	March 22, 2017
Trade name:	MEP Monitor
Common name:	MEP Monitor
Classification name:	Evoked Response Electrical Stimulator
Classification:	Class II Medical Device
Product Code:	GWF
Regulation number:	21 CFR 882.1870
Identification of predicate device:	MEP POD, Magstim Rapid² in K051864, MagPro magnetic stimulators in K061645 / K091940

Device description

The MEP Monitor is a small accessory device which is connected to the rear side of a MagPro magnetic stimulator. The MagPro magnetic stimulators are FDA cleared in K061645 and K091940.
The device in this submission is not used alone but is connected to the MagPro stimulators on the rear side of either of the 4 cleared stimulators.
The setup of the MEP Monitor is done in the MEP menu on the stimulator. The display on the stimulator shows a curve with the MEP response.

Indications for Use:
The MEP Monitor is an accessory for the MagPro stimulators (MagPro R30, MagPro R30 including MagOption, MagPro X100, and MagPro X100 including MagOption) and is intended to monitor evoked potentials.

Substantial Equivalence:
The MEP Monitor in this submission has the same characteristics as the predicate device, MEP Pod (K051864). The magnetic stimulators, to which the MEP Monitor is an accessory, have the same characteristics as the predicate stimulator and are substantial equivalent to this.

The MEP Monitor is CE-marked and complies with the Medical Device Directive 93/42/EEC. The MEP Monitor is developed and manufactured according to EN13485, “Medical devices – Quality management systems – Requirement for regulatory purposes”.

Area	New Device **MEP Monitor** **accessory to MagPro Stimulators (K061645 and K091940)** **Tonica Elektronik A/S**	Predicate Device **MEP POD (K051864)** **Included with Magstim Rapid^2** **Magstim Company Ltd.**	Conclusion
Indications for use	MEP Monitor: The MEP Monitor is an accessory for the MagPro stimulators (MagPro R30, MagPro R30 including MagOption, MagPro X100, and MagPro X100 including MagOption) and is intended to monitor evoked potentials. Magnetic Stimulator: The MagPro family is intended to be used for magnetic stimulation of peripheral nerves for diagnostic purposes.	MEP Pod: The device will when connected to a stimulator monitor the MEP response in peripheral nerves and display this on the stimulator. Magnetic Stimulator The Magstim Rapid2 magnetic nerve stimulator systems are intended for the stimulation of peripheral nerves.	Identical
Energy used	MEP Monitor: Power supported from the magnetic stimulator Magnetic stimulator: Power Supply: 100-120V Mains. Pulses, max energy 280J	MEP Pod: Power supported from the magnetic stimulator Magnetic stimulator: Power Supply: 115V Mains. Pulses, max energy 225J	MEP: Identical. Magnetic stimulator: Similar energy system used.
Mechanical data	MEP Monitor: Dimensions: (HxWxD:) 7.2 x 3.7 x 1.6 in Weight: 1.5 lb Magnetic stimulators: 33 kg/72 lbs 58 kg/128 lbs 35 kg/ 77 lbs 60 kg/ 132 lbs	MEP Pod: The MEP Pod has smaller dimensions than MEP Monitor. Magnetic stimulator: 27 kg / 60 lbs	Similar. Differences are of no importance.
Design	MEP Monitor: The Motor Evoked Potential (MEP) Monitor is an optional component which allows the user to capture EMG signals and display them on the MagPro UI. Device with 1 channel input. Isolated input DIN-connector (Body Floating). Directly connected to the rear panel of the magnetic stimulator device.	MEP Pod: The Motor Evoked Potential (MEP) Pod is an optional component which allows the user to capture EMG signals and display them on the Magstim Rapid^2 UI. Device with 2 channel input. Isolated input connectors (Body Floating). Connected via a long cable to the magnetic stimulator device.	MEP: Identical. MEP Monitor has only 1 channel.

Area	New Device **MEP Monitor** **accessory to MagPro Stimulators (K061645 and K091940)** **Tonica Elektronik A/S**	Predicate Device **MEP POD (K051864)** **Included with Magstim Rapid^2** **Magstim Company Ltd.**	Conclusion
	The MEP Monitor is designed to be used with surface electrodes only. Supports connections of standard electrode cables and surface electrodes. Magnetic stimulator: Magnetic stimulation is equivalent to current stimulation. The principle of magnetic stimulation is implicit in Faraday's law, which describes that a time-varying magnetic field induces a current in a conductor (tissue). Application areas of magnetic stimulation are a sub-set of the application areas for current stimulation. The device consist of a unit comprising power supply, capacitor bank, high voltage electronics, control electronics and user interface (controls) with knobs and display on the front panel. User interface is menu-driven and computer controlled. A magnetic coil is connected to the device to generate a magnetic field.	The MEP Pod is designed to be used with surface electrodes only. Supports connections of standard electrode cables and surface electrodes. Magnetic stimulator: Magnetic stimulation is equivalent to current stimulation. The principle of magnetic stimulation is implicit in Faraday's law, which describes that a time-varying magnetic field induces a current in a conductor (tissue). Application areas of magnetic stimulation are a sub-set of the application areas for current stimulation. The device consist of a unit comprising power supply, capacitor bank, high voltage electronics, control electronics and user interface (controls) with knobs and a display with touch screen control. User interface is menu-driven and computer controlled. A magnetic coil is connected to the device to generate a magnetic field.	Magnetic stimulator: Identical. The design of the devices is basically the same, with use of a capacitor bank and high voltage electronics to generate a magnetic field in a magnetic coil.
Performance	MEP Monitor: Time base max.: 100ms Sensitivity: 50µV/Div – 10mV/Div Filters: 1Hz-20kHz Magnetic stimulator: MagPro R30 Waveforms: Biphasic. Single pulses, train pulses. Max. stim. Frequency: 30 pulses per second.	MEP Pod: Time base max.: 500ms Sensitivity: 50µV/Div – 10mV/Div Filters: 2Hz-10kHz Magnetic stimulator: Waveforms: Biphasic and Biphasic Burst. Single pulses, train pulses. Max. stim. Frequency: 60 pulses per second.	MEP: Similar characteristics Magnetic stimulator: MagPro R30: Similar

Area	New Device **MEP Monitor** **accessory to MagPro Stimulators (K061645 and K091940)** **Tonica Elektronik A/S**	Predicate Device **MEP POD (K051864)** **Included with Magstim Rapid^2** **Magstim Company Ltd.**	Conclusion
	MagPro R30 incl. MagOption: Waveforms: Biphasic, Monophasic. Single pulses, train pulses, dual/twin pulses. Max. stim. Frequency: 30 pulses per second MagPro X100: Waveforms: Biphasic, Biphasic Burst, Monophasic. Single pulses, train pulses. Max. stim. Frequency: 100 pulses per second MagPro X100 incl. MagOption: Waveforms: Biphasic, Halfsine, Biphasic Burst, Monophasic.		MagPro R30 incl. MagOption: Waveforms identical. Single and train pulses identical. Dual/twin pulses are where 2 pulses is given as a double pulse. This is equivalent with the setup in Biphasic Burst mode where the Super Rapid2 is able to stimulate with up to 10 pulses. This mode is also called Theta Burst. The use of double pulses is also well known for current stimulation. Max. stim. Frequency identical or lower MagPro X100: Waveforms identical with predicate devices. Single and train pulses identical. Max. stim. Frequency of 100 pulses per second is higher than the Magstim Super Rapid^2 with 60pps. The output power from the MagPro is very limited at high repetition rates because the charging of the power electronic is not capable building up the full power between the pulses. At 100 pps the output power from MagPro is only 30% of full power at 15pps. High stimulation frequency is normal for current stimulator devices. E.g. the current stimulator for the Neuro diagnostic device Keypoint (K944547) with max. stim. frequency of 200Hz (pps) and Digitimer DS7A (K051357) with max. 1000pps. Stimulation at high frequency up to 100 pps is within the already accepted range for current stimulators on the US marked. MagPro X100 incl. MagOption: Waveforms identical. The Halfsine waveform is based on the normal Biphasic waveform. But the Halfsine waveform is not

Area	New Device **MEP Monitor** **accessory to MagPro Stimulators (K061645 and K091940)** **Tonica Elektronik A/S**	Predicate Device **MEP POD (K051864)** **Included with Magstim Rapid^2** **Magstim Company Ltd.**	Conclusion
	Single pulses, train pulses, dual pulses. Max. stim. Frequency: 100 pulses per second		as powerful as the Biphasic waveform. Halfsine waveform is also similar to the Monophasic waveform. Single and train pulses identical. Dual/twin pulses are where 2 pulses is given as a double pulse. This is equivalent with the setup in Biphasic Burst mode where the Super Rapid2 is able to stimulate with up to 10 pulses. This mode is also called Theta Burst. The use of double pulses is also well known for current stimulation. Max. stim. Frequency of 100 pulses per second is higher than the Magstim Super Rapid^2 with 60pps. The output power from the MagPro is very limited at high repetition rates because the charging of the power electronic is not capable building up the full power between the pulses. At 100 pps the output power from MagPro is only 30% of full power at 15pps. High stimulation frequency is normal for current stimulator devices. E.g. the current stimulator for the Neuro diagnostic device Keypoint (K944547) with max. stim. frequency of 200Hz (pps) and Digitimer DS7A (K051357) with max. 1000pps. Stimulation at high frequency up to 100 pps is within the already accepted range for current stimulators on the US marked.

Testing

The MEP Monitor together with the MagPro magnetic stimulators comply with the standard for electrical safety standard, IEC 60601-1 v3.1, and have been tested at a certified test center, UL Demko. EMC testing has been performed for compliance with the EMC standard, IEC 60601-1-2:2007 (3rd edition), Clause 6.1 Emission and Clause 6.2 Immunity.

List of latest test reports:

Electrical Safety reports Tests performed by: UL International Demko A/S www.ul-europe.com		Electromagnetic Compatibility Reports Tests performed by: Delta (Danish Electronics, Light & Acoustics) www.delta.dk	
Test report no.	Test report name	Test report no.	Test report name
E360406-D1002-1	UL IEC 60601-1 Medical electrical equipment ANSI/AAMI ES60601-1:2005/A2:2010	T209818-1 DANAK-19/15683	DELTA Test Report: EMC test

TABLE 1

Conclusion:

The MEP Monitor device, as well as the MagPro magnetic stimulators, has the same intended use as the predicate device and the same technological features. The MEP Monitor does not raise new issues of safety and effectiveness and is substantially equivalent to the predicate device.