DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 16, 2016

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

Re: K160280
Trade/Device Name: MagPro R20
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: February 1, 2016
Received: February 2, 2016

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 yours,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.05.16 16:55:59 -04'00'

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)*
K160280

Device Name
MagPro R20

Indications for Use *(Describe)*
MagPro R20 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

Submitter's Information

Name of 510(k) owner:	Tonica Elektronik A/S Lucernemarken 15 DK-3520 Farum, Denmark
Phone:	+45 4499 8444
Fax:	+45 4499 1544
Contact person:	Lise Terkelsen
Preparation date:	May 13th, 2016
Trade name:	MagPro R20
Common name:	MagPro R20
Classification name:	Evoked Response Electrical Stimulator
Classification:	Class II Medical Device
Product Code:	GWF
Regulation number:	21 CFR 882.1870
Identification of predicate device:	MagPro R30, K061645

Device description
MagPro R20 is a Magnetic stimulator used for Magnetic stimulation.
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 MagPro R20 is connected to a Magnetic Coil which transfers the magnetic stimulation to the tissue.

The MagPro R20 consists of power electronics to generate the magnetic field in the Magnetic Coil. The MagPro R20 is controlled via a user interface, enabling the operator to overview all functions, stimulus sequences, controls, status and measured data. The MagPro R20 has a built-in computer and 2 small displays.
The magnetic pulse is Biphasic waveform and the stimulator can stimulate with a frequency of up to 20 pulses per second (pps).

Intended Use:
The MagPro R20 is intended for stimulation of peripheral nerves for diagnostic purposes.

Substantial Equivalence:
The MagPro R20 in this submission has the same characteristics as the predicate device, MagPro R30 (K061645). Stimulation of peripheral nerves is the intended application which applies to both devices.

They consist of a unit comprising power electronic to generate the magnetic fields in a Magnetic Coil. All includes a user interface to control the device via knobs and a display on the front panel.

The waveforms for the MagPro R20 and the MagPro R30 are biphasic. The maximum stimuli frequency is 30 pulses per second for MagPro R30 while 20 pulses per second for MagPro R20.

The MagPro R20 is CE-marked and complies with the Medical Device Directive 93/42/EEC. The MagPro R20 is developed and manufactured according to EN13485, “Medical devices – Quality management systems – Requirement for regulatory purposes”.

Area	New Device ***MagPro R20*** **Tonica Elektronik A/S**	Predicate Device ***MagPro R30*** **Tonica Elektronik A/S**	Conclusion
Indications for use	Is intended to be used for stimulation of peripheral nerves for diagnostic purposes.	Is intended to be used for stimulation of peripheral nerves for diagnostic purposes.	Identical
Energy used	Power Supply via Isolation Transformer Power Supply: 120V~, 50/60 Hz. Power consumption: Maximum 800VA	Power Supply via Isolation Transformer Power Supply: 120V~, 50/60Hz Power consumption: Maximum 2300VA	Identical Lower power consumption
Mechanical data	Dimensions (HxWxD): 150 x 390 x 440mm Weight: 20 kg / 44 lbs	Dimensions (HxWxD): 210 x 530 x 400mm Weight: 36kg / 79 lbs	R30 bigger and heavier than R20.
Pulse width	280 µsec Biphasic	280 µsec Biphasic	Identical
Console	MagPro R20 consists of a power module, a processor module and built in displays. The optional trolley supports the R20 and makes it moveable. The complete system is powered from an Isolation Transformer.	MagPro R30 consists of a power module, a processor module and a built in display. The optional trolley supports the R30 and makes it moveable. The complete system is powered from an Isolation Transformer.	Identical

User Interface	MagPro R20 has 2 displays
	• Intensity display
	  ◦ Coil temperature
	  ◦ Intensity
	• Menu display and indicators can show
	  ◦ Repetition rate
	  ◦ Pulses in train
	  ◦ Number of trains
	  ◦ Inter train interval
	  ◦ Start delay
	  ◦ Volume
		MagPro R30 has 1 display
		All parameter settings can be shown on the display.
		• Intensity
		• Repetition rate
		• Pulses in train
		• Number of trains
		• Inter train interval
		• Start delay
		• Amplitude
		• Realized di/dt
			Primary readout equivalent.
			
			MagPro R30 has a more complex interface. MagPro R20 is meant for everyday diagnostic purposes
			Same level of safety.

Area	New Device ***MagPro R20*** **Tonica Elektronik A/S**	Predicate Device ***MagPro R30*** **Tonica Elektronik A/S**	Conclusion
	• Status: enable/disable • Coil type	• Status: enable/disable • Coil temperature • Coil type • Available stimuli • Event log information and date/time • Treatment sequence can be stored and reused. Event log and Amplitude log can be exported. • Continuously readout of di/dt controlling the stability of the produced magnetic stimulation	

Testing

The MagPro R20 complies with the standard for electrical safety standard, IEC 60601-1 v3.1, and has been tested at a certified test center, UL Demko. EMC testing has been performed for compliance with the EMC standard, IEC 60601-1-2.

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-D1-CB	UL IEC 60601-1 Medical electrical equipment ANSI/AAMI ES60601-1:2005/A2:2010	T206073-1 DANAK-19/13416 Rev. A	DELTA Test Report: EMC test of MagPro R20
DK-38637-UL	CB certificate		

TABLE 1

Conclusion:

The MagPro R20 has the same intended use as the predicate device and the same technological features. The MagPro R20 does not raise new issues of safety and effectiveness and is substantially equivalent to the predicate device.