



Food and Drug Administration
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October 5, 2017

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

Re: K172667

Trade/Device Name: MagVita TMS Therapy w/MagPro R20
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: August 30, 2017
Received: September 5, 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 (DICE) 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 (DICE) 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,

William J. Heetderks -S
2017.10.05 13:52:32 -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

Indications for Use

510(k) Number (if known)
K172667

Device Name
MagVita TMS Therapy w/MagPro R20

Indications for Use (Describe)

The MagVita TMS Therapy – w/MagPro R20 is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

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
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Contact person: Lise Terkelsen
Email: lise.terkelsen@tonica.dk

Preparation date: August 30, 2017

Trade name: MagVita TMS Therapy w/MagPro R20

Common name: Transcranial Magnetic Stimulator

Classification name: Repetitive Transcranial Magnetic Stimulator for treatment of Major Depressive Disorder [21 CFR 882.5805, Product Code OBP]

Classification: Class II Medical Device

Predicate Devices: MagVita TMS Therapy w/MagPro R20, K170114

Special Controls: The 510k submission addressed the special controls required by regulation and specified in the FDA guidance document titled "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems"

MagVita TMS Therapy – w/MagPro R20

Device description

The MagVita TMS Therapy System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic fields to induce electrical currents directed at regions of the cerebral cortex. The MagVita TMS Therapy System is indicated for

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Transcranial magnetic stimulation (TMS) is a non-invasive technique for stimulating brain and neural tissue. The principle of magnetic stimulation is implicit in Faraday's law. The pulses of current are generated with a circuit containing a capacitor connected to the stimulating coil. With the capacitor charged to a certain level, the conducting state will cause the discharging of the capacitor through the coil. A magnetic field is generated proportional to this current. The rapid change in the magnetic field induces a current in conducting materials e.g. the body tissue. If the current induced in the human body is of sufficient amplitude and duration, it will excite neurons.

In the MagVita TMS therapy system TMS pulses are applied repetitively at a frequency of 10Hz. Such stimulation has been shown to be effective in modulating cortical excitability. The observed and documented increase in cortical excitability after high frequency (10Hz) repetitive transcranial magnetic stimulation has been shown to persist beyond the duration of the train of stimulation. Repetitive Magnetic stimulation with the MagVita TMS therapy system is applied to the human brain on the left dorsolateral prefrontal cortex (DLPFC).

The MagVita TMS Therapy w/MagPro R20 is an integrated system consisting of the following components:

- MagPro Stimulator and Trolley
 - MagPro R20
 - Trolley with holding arrangements
- Coils for MT determination and Depression Treatment
 - Coil MCF-B70
- Marking apparatus for locating treatment area
 - Marking plate for Coil MCF-B70
 - Pen for marking, Cap, Ruler
- Patient head fixation
 - Treatment Chair
 - Vacuum Pump and Vacuum pillow
 - Super Flexible Arm mounted on the trolley
- Isolation Transformer

The Modification

The difference between the cleared MagVita TMS Therapy w/MagPro R20 and the modified MagVita TMS Therapy w/MagPro R20 (this submission) is the replacement of the two MCF-B65 coils with one MCF-B70 coil.

Intended Use/Indication for Use:

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Standards:

The MagVita TMS Therapy System w/MagPro R20 has been tested and complies with the following standards

- ISO 13485:2012
- IEC60601-1
- IEC60601-1-2

Non-Clinical performance data:

The non-clinical performance testing of the components of the MagVita TMS Therapy System has been tested as required, and cleared by the FDA earlier on K170114.

These tests demonstrate that the MagVita TMS Therapy System is safe and effective for use in treatment of Major Depressive Disorder.

Substantial equivalence:

The MagVita TMS Therapy w/MagPro R20 is substantially equivalent to the predicate device (our own MagVita TMS Therapy w/MagPro R20 before the modification). The MagVita TMS Therapy w/MagPro R20 and the predicate device have identical intended use /indication for use, and the technological characteristics are similar such that they in our view can be considered equivalent.

The MagVita TMS Therapy w/MagPro R20 and the predicate device are both indicated for

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Design of the MagVita TMS Therapy w/MagPro R20 is similar to the predicate device as all systems apply Transcranial Magnetic Stimulation as repetitive pulse trains at 10Hz delivered as brief rapidly alternating magnetic fields to induce electrical currents over the prefrontal cortex.

Both the MagVita TMS Therapy and the predicate device have the same components consisting of TMS stimulator with software, electromagnetic coil and an articulated arm for positioning of the treatment coil. The operational procedures including system setup, patient preparations, motor threshold determination, coil positioning and treatment with predefined treatment stimulation parameters are identical.

MagVita TMS Therapy – w/MagPro R20

Characteristics of the Device as Compared to Predicate Device

Criteria	MagVita TMS Therapy w/MagPro R20 modification	MagVita TMS Therapy w/MagPro R20 K170114	Conclusion
Performance	Waveforms: Biphasic Frequency: 0.1 -20 pulses per second. Preset range of % MT: 50%-140%	Waveforms: Biphasic Frequency: 0.1 -20 pulses per second. Preset range of % MT: 50%-140%	Identical
	<u>Recommended standard treatment:</u> Stimulation Intensity: 120% MT (MT=Motor Threshold intensity) Repetition rate: 10 Hz Train duration: 4 sec Interval between pulses: 26 sec Numbers of pulses/session: 3000	<u>Recommended standard treatment:</u> Stimulation Intensity: 120% MT (MT=Motor Threshold intensity) Repetition rate: 10 Hz Train duration: 4 sec Interval between pulses: 26 sec Numbers of pulses/session: 3000	
	<u>Output Stimulation Parameters:</u> Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0 - 1.2 SMT Pulse width: 290 μ s (\pm 5%), Biphasic sinusoid waveform. Frequency Range: 0.1-20 pps (\pm 2%)	<u>Output Stimulation Parameters:</u> Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0 - 1.2 SMT Pulse width: 290 μ s (\pm 5%), Biphasic sinusoid waveform. Frequency Range: 0.1-20 pps (\pm 2%)	
Coil Configuration Cooling	Figure-of-eight coil Coil MCF-B70 Liquid cooling	Figure-of-eight coil Coil MCF-B65 Liquid cooling	Substantial equivalence of magnetic field properties is documented in Appendix A enclosed in section 12.
Design	<u>The system consists of:</u> 1. Mobile console 2. System software with GUI 3. Coil positioning system 4. Coil for MT and coil for treatment 5. Coil Fixture 6. Treatment chair 7. Head support system	<u>The system consists of:</u> 1. Mobile console 2. System software with GUI 3. Coil positioning system 4. Coil for MT and coil for treatment 5. Coil Fixture 6. Treatment chair 7. Head support system	
Standards met	Company complies with ISO 13485:2012.	Company complies with ISO 13485:2012	Identical
Electrical safety	Complies with IEC60601-1, IEC60601-1-1 and IEC60601-1-2.	Complies with IEC60601-1, IEC60601-1-1 and IEC60601-1-2.	Identical

Conclusion:

The SE comparison as documented in the Substantial Equivalence section together with the Appendix 1 regarding the coil properties demonstrates and supports the substantial equivalency of the modified MagVita TMS Therapy w/MagPro R20 to our own not-modified MagVita TMS Therapy w/MagPro R20.

The indication for use, the target population, the dosage, the treatment procedure, the treatment position and all relevant protocol parameters (intensity, repetition rate, number of pulses in a train, numbers of trains, number of treatment sessions) are identical for the modified MagVita TMS Therapy w/MagPro R20 and the predicate device.

The transducer design (figure-of-eight) is equivalent and the realized magnetic properties of the *MagVita TMS Therapy System* and the predicate device are substantial equivalent for the treatment coils.

The MagVita TMS Therapy w/MagPro R20 does not introduce any new safety considerations in comparison to the predicate device.