



Food and Drug Administration
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June 16, 2017

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

Re: K171481

Trade/Device Name: MagVita TMS Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: May 17, 2017
Received: May 19, 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,

William J. Heetderks -S
2017.06.16 12:07:00 -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)

K171481

Device Name

MagVita TMS Therapy System

Indications for Use (Describe)

The MagVita TMS Therapy System 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.

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MagVita TMS Therapy System

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: May 15, 2017

Trade name: MagVita TMS Therapy System

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: Neurostar TMS Therapy System, K160703
MagVita TMS Therapy System, K150641

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 System

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).

- MagPro Stimulator and Trolley
 - MagPro family
 - Trolley with holding arrangements
- Coil for MT determination
 - Coil C-B60
- Marking apparatus for locating treatment area
 - Marking plate for Coil C-B60
 - Pen for marking, Cap, Ruler
- Patient head fixation
 - Treatment Chair
 - Vacuum Pump and Vacuum pillow
 - Super Flexible Arm mounted on the trolley
- Coil for Depression Treatment
 - Coil Cool-B65 with Coil Cooler unit
- Isolation Transformer

MagVita TMS Therapy System

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 has been tested and complies with the following standards

- ISO 13485:2012
- IEC60601-1
- IEC60601-1-1
- 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 K091940 and K150641.

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 System is substantially equivalent to the predicate devices (our own MagVita TMS Therapy System and Neurostar TMS). The MagVita TMS Therapy System and the predicate devices have identical intended use /indication for use, and technological characteristics. The principles of operation, the output stimulation parameters and the materials are equivalent to the predicates. The modification to the device allows a range of inter-train intervals from 11 to 26 seconds, rather than the fixed 26 second duration, which will allow a reduction in treatment time from 37.5 minutes to a minimum of 18.8 minutes.

The MagVita TMS Therapy System and the predicate devices are all 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 System is similar to the predicate device as both 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 System and the predicate devices 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

MagVita TMS Therapy System

positioning and treatment with predefined treatment stimulation parameters are essentially the same.

Characteristics of the Device as Compared to Predicate Devices

Criteria	MagVita TMS Therapy System	MagVita TMS Therapy System (K150641)	NeuroStar TMS Therapy System (K160703)
Performance	Waveforms: Biphasic. Frequency: 0.1 -30 pulses per second or 0.1 -100 pulses, depending on model	Waveforms: Biphasic. Frequency: 0.1 -30 pulses per second or 0.1 -100 pulses, depending on model	Waveforms: Biphasic Frequency: 0.1 -30 pulses per second.
	<u>Recommended standard treatment:</u> Stimulation Intensity: 120% MT Repetition rate:10 Hz Train duration: 4 sec Inter-train interval: 11-26 sec Pulses/session: 3000 Treatment duration: 18.8 min.	<u>Recommended standard treatment:</u> Stimulation Intensity: 120% MT Repetition rate: 10 Hz Train duration: 4 sec Inter-train interval: 26 sec Pulses/session: 3000 Treatment duration: 37 min.	<u>Recommended standard treatment:</u> Stimulation Intensity: 120% MT Repetition rate: 10 Hz Train duration: 4 sec Inter-train interval: 11-26 sec Pulses/session: 3000 Treatment duration: 18.8 min.
	<u>Output Stimulation Parameters:</u> Amplitude in Standard Motor Threshold (SMT) units : 0 – 1.7 Pulse width: 290 μ s, Biphasic sinusoid waveform. Frequency Range: 0.1-30 pps or 0.1-100 pps, depending on model	<u>Output Stimulation Parameters:</u> Amplitude in Standard Motor Threshold (SMT) units: 0 - 1.7 Pulse width: 290 μ s, Biphasic sinusoid waveform. Frequency Range: 0.1-30 pps or 0.1-100 pps, depending on model	<u>Output Stimulation Parameters:</u> Amplitude in Standard Motor Threshold (SMT) units: 0.22 - 1.6 Pulse width: 185 μ s (\pm 10%), Biphasic sinusoid waveform.. Frequency Range: 0.1-30 pps
Coil Configuration	Figure-of-eight coil Air core	Figure-of-eight coil Air core	Figure-of-eight coil Ferromagnetic core
Cooling	Liquid cooling	Liquid cooling	Ferrofluidic cooling
Standards met	Company complies with ISO 13485:2012.	Company complies with ISO 13485:2012	Company complies with ISO 13485:2003
Electrical safety	Complies with IEC60601-1 3 rd edition, and IEC60601-1-2.	Complies with IEC60601-1 3 rd edition, and IEC60601-1-2.	Complies with IEC60601-1 and IEC60601-1-2.

Conclusion:

The above comparison, demonstrates and supports the substantial equivalency of the *MagVita TMS Therapy System* to our own *MagVita TMS Therapy System* and the *NeuroStar TMS Therapy System*.

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 *MagVita TMS Therapy System* and the predicate devices.

MagVita TMS Therapy System

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

The reliability of the positioning method used by the *MagVita TMS Therapy System* is, based on the direct relationship of the underlying cortical brain anatomy to the patient's scalp, as is the method used in the predicate devices. The method for identifying the correct treatment position in the MagVita TMS Therapy System is at least as effective as the method employed by the predicate devices.

On the basis of the only modification of the treatment parameter, the *MagVita TMS Therapy System* does not introduce any new safety considerations in comparison to the predicate devices

All other identified differences between the three systems are minor and without impact on safety or efficacy.