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

July 31, 2015

Tonica Elektronik A/S
Lise Terkelsen
Regulatory Affairs/ Quality Assurance Specialist
Lucernemarken 15
DK-3520 Farum, Denmark

Re: K150641
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: March 10, 2015
Received: March 13, 2015

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,

Carlos L. Pena -S

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)*
K150641

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.

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

Preparation date:	July 24, 2015
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 Device:	NeuroStar TMS Therapy Systems (K083538, K133408) 21 CFR 882.5805, Repetitive Transcranial Magnetic Stimulation Product code: OBP Device Class: II

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 as effective as the predicate device 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 System is an integrated system consisting of the following components:

- 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

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 K061645, K071821 and K091940.

These tests along with the supportive clinical information from the predicate device demonstrate that the MagVita TMS Therapy System is as safe and effective as the predicate device for use in treatment of Major Depressive Disorder.

Substantial equivalence:

The MagVita TMS Therapy System is substantially equivalent to the predicate device (Neurostar TMS Therapy® System). The MagVita TMS Therapy System and the predicate device have identical intended use /indication for use, and the technological characteristics are very similar such that they in our view can be considered equivalent.

The MagVita TMS Therapy System 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 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 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 essentially the same.

Characteristics of the Device as Compared to Predicate Device*

Area	MagVita TMS Therapy System	NeuroStar TMS Therapy System Neuronetics Inc. (K083538,K133408)
Performance	Waveforms: Biphasic. Frequency: 0.1 -30 pulses per second or 0.1 -100 pulses, depending on model Preset range of % MT: 0% -140%	Waveforms: Biphasic Frequency: 0.1 -30 pulses per second. Preset range of % MT: 80% -140%
	Recommended standard treatment: 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	Recommended standard treatment: 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
	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0 - 1.7 SMT Pulse width: 290 µs (±5%), Biphasic sinusoid waveform. Frequency Range: 0.1-30 pps (±2%) or 0.1-100 pps, depending on model	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0.22 - 1.6 SMT Pulse width: 185 µs (±10%), Biphasic sinusoid waveform. Frequency Range: 0.1-30 pps (±2%)
Coil Configuration Cooling	Figure-of-eight coil Air core Liquid cooling	Figure-of-eight coil Ferromagnetic core Ferrofluidic cooling
Standards met	Company complies with ISO 13485:2012.	Company complies with ISO 13485:2003
Electrical safety	Complies with IEC60601-1, IEC60601-1-1 and IEC60601-1-2.	Complies with UL60601-1 and UL60601-1-2

*For a more comprehensive comparison of devices please refer to section 12 Substantial Equivalence Comparison

Conclusion:

The above comparison, demonstrates and supports the substantial equivalency of the *MagVita TMS Therapy System* to 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 device *NeuroStar 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 device are substantial equivalent for the two coils.

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 device. 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 device.

The *MagVita TMS Therapy System* does not introduce any new safety considerations in comparison to the predicate device.

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