August 14, 2018

Tonica Elektronik A/S
Sanne Jessen
Medical Advisor
Lucernemarken 15
Farum, 3520 Dk

Re: K173620
Trade/Device Name: Mag Vita TMS Therapy System w/Theta Burst Stimulation
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: July 10, 2018
Received: July 13, 2018

Dear Sanne Jessen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173620

Device Name
MagVita TMS Therapy System w/Theta Burst Stimulation

Indications for Use *(Describe)*
The MagVita TMS Therapy System w/ Theta Burst Stimulation 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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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:	Sanne Barsballe Jessen Medical Advisor Email: sj@magventure.com Phone: +45 44390418 Other: Jan Kjoeller Email: jk@tonica.dk

Preparation date:	August 10, 2018
Trade name:	MagVita TMS Therapy System w/ Theta Burst Stimulation
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 System (K150641, K171481, K171967 and K172667) 21 CFR 882.5805, Repetitive Transcranial Magnetic Stimulation Product code: OBP Device Class: II

510(k)

MagVita TMS Therapy System w/Theta Burst Stimulation

Device description

The MagVita TMS Therapy System w/Theta Burst Stimulation is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic fields to induce electrical currents targeting specific regions of the cerebral cortex. The MagVita TMS Therapy System w/ Theta Burst Stimulation is indicated for the treatment of Major Depressive Disorder (MDD) 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. The standard-of-care FDA approved TMS protocol for treatment of MDD uses repetitive transcranial magnetic pulses applied at a frequency of 10 Hz. Such stimulation has been shown to be effective in modulating cortical excitability. The observed and documented increase in cortical excitability after high frequency (10 Hz rTMS) repetitive TMS (rTMS) has been shown to persist beyond the duration of the train of stimulation, and 10 Hz rTMS on the Left-Dorsolateral prefrontal cortex (L-DLPFC) has been shown to be effective and safe in the treatment of MDD. A newer form of the TMS, called intermittent Theta Burst Stimulation (iTBS), mimics the endogenous theta rhythms of the human brain, and has been shown to evoke equally potent excitatory effects. Intermittent TBS provides bursts of three individual stimuli at a rate of 50 Hz (i.e. 20 ms apart), repeated at 5 Hz (i.e. 200 ms between burst) mimicking the theta rhythm of the brain. Thus, the iTBS protocol is more demanding in terms of stimulator output. The clinical performance is based on the fact that the actual individual stimuli are of equal intensity, to ensure that a constant dose of stimuli is delivered during treatment.
MagVita TMS therapy system w/Theta Burst stimulation is applied to the human brain of the left dorsolateral prefrontal cortex (L-DLPFC) using iTBS.

The MagVita TMS Therapy System w/ Theta Burst Stimulation is an integrated system consisting of the following components:

- MagPro Stimulator and Trolley
  - MagPro family
  - Trolley with holding arrangements
- Coil for MT determination and Depression treatment
  - Coil Cool-B70 with Coil Cooler Unit
- Marking apparatus for locating treatment area
  - Marking plate for Coil Cool-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

Intended Use/Indication for Use:
The MagVita TMS Therapy System w/Theta Burst Stimulation and the predicate device are 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.

Performance Standards:
The MagVita TMS Therapy System w/Theta Burst Stimulation 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 w/ Theta Burst Stimulation has been tested as required according to the standards listed above.
To establish substantial equivalency for the new coil and the predicate devices we have performed a comparative testing of the magnetic field distribution for the Cool-B70 coil and the predicate devices, that determines that the magnetic spatial distribution is substantially equivalent.
The MagVita TMS Therapy System w/Theta Burst Stimulation consists of components that are identical to those of the predicate devices. The New Device is identical to the predicate devices in terms of biocompatibility, design elements, such as cable lengths, coil materials, size and coil windings as well as cooling media, isolation design and functionalities. All coils are subject to high-voltage tests and leakage current tests to ensure safety.

In addition, the MagVita TMS Therapy System w/Theta Burst Stimulation has been verification tested to ensure that the intensity of the individual stimuli in iTBS is equal and kept constant. The clinical performance is based on the fact that the actual individual stimuli are of equal intensity, to ensure that a constant dose of stimuli is delivered during treatment.

We have also tested the device according to IEC60601 3rd edition and verified that the device complies with the specified permissible sound pressure levels. The device also complies with the permissible thresholds for exposure defined by the Occupational Safety and Health Administration (OSHA).
These tests provide evidence that the MagVita TMS Therapy System w/Theta Burst Stimulation does not pose any risk for potential hearing reduction or loss in either patients or operators.

Clinical performance data:
The effectiveness, safety and tolerability of iTBS have been demonstrated in a large randomized, multicenter trial. iTBS has similar effectiveness and side effect profile compared to standard-of-care 10 Hz rTMS. Based on performance testing, the MagVita TMS Therapy System w/Theta Burst Stimulation, is as safe and effective and performs as well as the predicate devices with enhanced ease of use and reduced treatment time to the benefit of both patient and operator.

Substantial equivalence:
The MagVita TMS Therapy System w/Theta Burst Stimulation is substantially equivalent to the predicate device, MagVita TMS Therapy System. The MagVita TMS Therapy System w/Theta Burst Stimulation and the predicate device have identical indication for use, and the technological characteristics are very similar such that they can be considered equivalent. The clinical performance and effectiveness, as well as tolerability and side effect profile for the new device and the predicate devices are substantially equivalent.

Design of the MagVita TMS Therapy System w/Theta Burst Stimulation is identical to the predicate device MagVita TMS Therapy System as both systems apply Transcranial Magnetic Stimulation at an intensity of 1.2xMT (120% of MT) as repetitive pulse trains delivered as brief rapidly alternating magnetic fields to induce electrical currents over the prefrontal cortex.
Both the MagVita TMS Therapy System w/Theta Burst Stimulation and the predicate device MagVita TMS Therapy System consist on the same components, that is 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 and coil positioning are essentially the same. The two systems only differ in predefined treatment stimulation parameters.

Characteristics of the Device as Compared to Predicate Devices*

Area	**New Device MagVita TMS Therapy System w/ Theta Burst Stimulation**	**Predicate Device MagVita TMS Therapy System Tonica Elektronik A/S (K150641, K171481, K171967 and K172667)**
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 or 0.1 -100 pulses, depending on model Preset range of % MT: 0% - 140%

Area	**New Device** **MagVita TMS Therapy System w/** **Theta Burst Stimulation**	**Predicate Device** **MagVita TMS Therapy System** **Tonica Elektronik A/S** **(K150641, K171481, K171967 and K172667)**
	<u>iTBS treatment protocol:</u> Stimulation Intensity: 120% MT (MT=Motor Threshold intensity) Repetition rate: 50 Hz (5 pulses pr sec) Train duration: 2 sec Interval between Trains: 8 secs Burst pulses: 3 Bursts : 200 Inter pulse interval: 20 msec Number of trains : 20 Numbers of pulses/session: 600 Total duration: 3 min and 9 sec	<u>Standard treatment:</u> Stimulation Intensity: 120% MT (MT=Motor Threshold intensity) Repetition rate: 10 Hz Train duration: 4 sec Interval between pulses: 11-26 sec Number of trains: 75 Numbers of pulses/ session: 3000 Total duration: 19-37.5 min.

Area	**New Device** **MagVita TMS Therapy System w/** **Theta Burst Stimulation**	**Predicate Device** **MagVita TMS Therapy System** **Tonica Elektronik A/S** **(K150641, K171481, K171967 and K172667)**
	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0 - 1.7 SMT The clinical performance of TBS is dependent on the fact that the stimuli are of equal intensity. At the relevant TBS intensities required in the treatment setting, the individual intensity of the three stimuli is kept constant (i.e. at maximum a 1% drop referred to maximum machine output between the first stimuli and the third stimuli in a burst).	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0 - 1.7 SMT
Coil Configuration Cooling	Figure-of-eight coil Air core Liquid cooling	Figure-of-eight coil Air core Liquid cooling
Standards met	Company complies with ISO 13485:2012.	Company complies with ISO 13485:2012.
Electrical safety	Complies with IEC60601-1 and IEC60601-1-2.	Complies with IEC60601-1 and IEC60601-1-2.

*For a more comprehensive comparison of devices please refer to section 12 Substantial Equivalence Comparison and to section 20 Clinical Performance.

Conclusion:
The indication for use, the target population, the treatment procedure and the treatment position are all 100 % identical for the MagVita TMS Therapy System w/Theta Burst Stimulation and the predicate device MagVita TMS Therapy System.
The protocol parameters are not equivalent in terms of dosage, repetition rate, number of pulses in a train or the number of trains. Hence, the dosage is much smaller for the New Device, whereas the repetition rate in contrast is higher. The intensity is identical for the MagVita TMS Therapy System w/Theta Burst Stimulation and the predicate devices. However, the iTBS protocol is more demanding in terms of stimulator output, and the MagVita TMS Therapy System w/Theta Burst Stimulation delivers stimuli of equal intensity, thereby verifying that the dose is maintained throughout the course of treatment.
The performance and the clinical effectiveness are substantially equivalent to that of the predicate devices, and the iTBS protocol with MagVita TMS Therapy System w/Theta Burst Stimulation in addition offers advantages over the predicate devices in terms of treatment duration to the benefit of the patient as well as the operator.

The transducer design (figure-of-eight) is equivalent, the magnetic properties of the MagVita TMS Therapy System w/Theta Burst Stimulation and the predicate devices, as well as the realized magnetic properties are substantially equivalent for the coils (K172667). Additionally, the new device offers the advantage that the same coil can be used for MT determination and treatment to the benefit of the Operator.

The reliability of the positioning method used by the MagVita TMS Therapy System w/Theta Burst Stimulation is, based on the direct relationship of the underlying cortical brain anatomy to the patient’s scalp, identical to the method used for the predicate device, MagVita TMS Therapy System and previously FDA cleared (K150641 and K171481).

The MagVita TMS Therapy System does not introduce any new safety considerations in comparison to the predicate devices based on clinical trial data.

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

The above comparison demonstrates and supports the substantial equivalency of the MagVita TMS Therapy System w/Theta Burst Stimulation to the predicate device, MagVita TMS Therapy System.