August 9, 2020

Tonica Elektronik A/S
Sanne Jessen
Medical Advisor, MSc, PhD
Lucernemarken 15
DK-3520 Farum, Denmark

Re: K193006
Trade/Device Name: MagVenture TMS Therapy - for adjunctive treatment of OCD, MagVenture TMS Therapy system
Regulation Number: 21 CFR 882.5802
Regulation Name: Transcranial Magnetic Stimulation System For Neurological And Psychiatric Disorders And Conditions
Regulatory Class: Class II
Product Code: QCI
Dated: April 29, 2020
Received: May 6, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K193006

Device Name
MagVenture TMS Therapy System

Indications for Use *(Describe)*
The MagVenture TMS Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

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
Phone/ Fax: +45 4499 8444 / +45 4499 1544

Contact person: Sanne Barsballe Jessen
Medical Advisor
Email: sj@magventure.com
Office: +453840 8449
Cell: +45 3119 9516

Other:
Jan Kjoeller
Email: jk@tonica.dk

Preparation date: August 8, 2020

Trade names: MagVenture TMS Therapy system
MagVenture TMS Therapy system – for adjunctive treatment of OCD

Common name: Transcranial Magnetic Stimulator

Classification name: Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions [21 CFR 882.5802] [Product Code QCI - Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder]

Classification:

Class II Medical Device

Predicate Devices:

Primary Predicate
Brainsway Deep Transcranial Magnetic Stimulation (DTMS) system, HAC – H7 coil (DEN170078, K183303)
21 CFR 882.5802, Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions
Product Code: QCI - Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder

Class II

Predicates
MagVenture TMS Therapy system (K150641, K171481, K171967, K172667, K173620)
21 CFR 882.5805, Repetitive Transcranial Magnetic Stimulation
Product code: OBP
Device Class: II

Device description

The MagVenture TMS Therapy system - for adjunctive treatment of OCD 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 MagVenture TMS Therapy system - for treatment of OCD is indicated as an adjunct for the treatment of adult patients who are suffering from Obsessive-Compulsive Disorder (OCD). MagVenture TMS Therapy system has previously obtained FDA clearance for treatment of major depressive disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode (K150641, K171481, K171967, K172667, K173620).

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 cleared TMS protocol for treatment of OCD uses repetitive transcranial magnetic pulses applied at a frequency of 20 Hz. The safety and effectiveness for treatment of OCD have been established in a clinical trial that lead to an FDA De Novo clearance of the primary predicate device, the Brainsway DTMS system. The present 510(k) does not include new pivotal data, but includes clinical trial data on more than 500 subjects treated with the MagVenture TMS Therapy System, in order to demonstrate performance and safety. Treatment of OCD is applied to the human brain of the bilateral dorsomedial prefrontal cortex (DMPFC) using 20 Hz TMS for 18 min. The treatment parameters are identical to those recommended by the Primary Predicate Device.

The MagVenture TMS Therapy system – for adjunctive treatment of OCD is an integrated system consisting of the following components:

- MagPro Stimulator and Trolley
  - MagPro Family (R30, R30 w. MagOption, X100, X100 w. MagOption)
  - Trolley with holding arrangements
- Coil for MT determination and OCD treatment
  - Coil Cool D-B80 with Coil Cooler Unit
- Marking apparatus for locating treatment area
  - 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

The MagVenture TMS Therapy system is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

The intended use is identical to that of the Primary Predicate Device.

Performance Standards:

The MagVenture TMS Therapy system - for adjunctive treatment of OCD has been tested and conforms with the following standards

- ISO 13485:2016
- IEC60601-1
- IEC60601-1-2

Non-Clinical performance data:

The contents of this 510(k) complies with the FDA Guidance Document: “Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems - Guidance for Industry and Food and Drug Administration Staff”.
The non-clinical performance testing of the components of the MagVenture TMS Therapy system - for treatment of OCD has been tested as required according to the standards listed above. All components, except the Cool D-B80 coil, have previously been cleared by the FDA, see K150641, K171481, K172667 and K173620.
The MagVenture TMS Therapy system – for adjunctive treatment of OCD consists of components that are identical to those of the predicate device, with the exception of the Cool D-B80 coil. The new coil is identical to the predicate device in terms of biocompatibility, design elements, such as cable lengths, coil materials, cooling media,

isolation design and functionalities. All coils are subject to high-voltage tests and leakage current tests to ensure safety.
To establish substantial equivalency for the new coil, Cool D-B80, and the primary predicate device, especially the HAC – H7 coil, we have performed substantial equivalence comparisons for testing and performance as described in Section 4 of the FDA's Class II Special Controls Guidance document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems.
We have performed a comparative testing of the magnetic field distribution for the Cool D-B80 coil and compared to that of the primary predicate device. This comparison determines that the magnetic spatial distribution is substantially equivalent. Both coils are so-called double cone coils, containing two coils that do not overlap, and allows for a deeper and broader stimulation of the cortex. We have provided information about magnetic field characteristics, including linearity of output level, magnetic field strength gradients, output waveform and magnetic field spatial distribution according to the Special Controls Guidance document, Section 4 as mentioned above. In addition, we have provided magnetic field characteristics for other, different relevant clinical depths of the human brain than those specified in the Special Controls Guidance and in the De Novo Summary of the Primary Predicate Device, which limits information to 2 cm depth.

In addition, we have modelled the magnetic properties of the New Device and the Primary Predicate Device, the HAC-7 coil. Our coil model calculations are based on the concept of well-established scientific methods (1).
The results of the e-field modelling of the HAC-7 coil is in line with the Manufacturer information provided in the De Novo Summary for the primary predicate device, DEN170078. The results of the e-field model show the magnetic field strength in the cortex for the two coils. This shows that the Cool D-B80 coil is able to reach the deeper underlying cortical layers similarly to the HAC – H7 coil. Based on the modelling, it is therefore concluded, that the magnetic field properties of the Cool D-B80 coil is substantially equivalent to the primary predicate device, HAC – H7 in terms of magnetic field properties and realized magnetic field properties. The modelling was used to support the technological comparison provided.

We have also provided information about the magnetic field spatial distribution of the new coil superimposed on T1-weighted MRI coronal, sagittal, and axial 1 cm slices. These images support the substantial equivalence comparisons determination and together with the above information, further supports the substantial equivalence of the new device compared to the primary predicate device, HAC-7.

We have also tested the new 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 MagVenture TMS Therapy system does not pose any risk for potential hearing reduction or loss in either patients or operators.

Clinical performance data:

This 510(k) does not contain any pivotal clinical trial data related to the new device. The substantial equivalency was established based on similar technological characteristics, but we have provided some clinical trial data to support the safety of the new device. The clinical evidence submitted also supports the safety and use of the new device as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).
A number of clinically relevant scientific references including more than 500 subjects treated with MagVenture TMS Therapy using the Cool D-B80 coil have been included with full text, as well as a summary and rationale for how these references support SE determination and/or safety and effectiveness for the new device for the proposed indication for use and for the proposed treatment protocol.

The primary predicate device De Novo Summary refers to a publication by Carmi et al. (2), who published the results of their pivotal trial supporting the De Novo, DEN170078. This study included a total of n=99, of which n= 50 received active TMS treatment. The proposed indication for use and treatment protocol are identical to that of the primary predicate device.

The new device is already cleared for use in both Europe and Canada and has been used in clinical research for a number of years.
Most of the clinical research performed using the new device has been conducted outside the USA. Most research has focused on the use of the new device for treatment of treatment-resistant depression (TRD) or major depressive disorder (MDD). There has been considerable interest in investigating the DMPFC as a target for TRD/MDD. Though MDD/TRD and OCD are distinct psychiatric disorders they share common underlying deficits in cortical networks. Thus, it is therefore relevant to demonstrate that the new device can be used to deliver TMS at the right treatment location, DMPFC, and that this can lead to modulation of deeper brain structures and long-range networks that are important in the recovery of symptoms of OCD as well as MDD. In addition, the clinical trials also demonstrate that the new device can be used efficiently and routinely to determine MT in the leg or foot, in a substantially equivalent way to the primary predicate device. Importantly, the clinical data also helps demonstrate safety for the new device.

In summary, the literature referenced includes a total of 521 subjects treated with TMS or iTBS protocols effectively targeting the DMPFC using the new device with treatment intensity defined based on the use of Leg MT. It is noteworthy that most of the clinical investigations have utilized treatment intensities that are higher than those used by the primary predicate device for OCD as reported by Carmi et al (2). Thus, treatment with the new device at an intensity of 100% Leg MT might be even more tolerable and safer in comparison with higher intensity. Despite this difference in intensity, the clinical data for the new device shows that the treatment overall is well-tolerated and safe. The treatment with the new device does not introduce any new adverse or serious adverse events. In fact, the side effect profile resembles that of standard TMS and iTBS treatment of the L-DLPFC and it is also equivalent to the side effect profile of the primary predicate device.
We therefore conclude that the treatment with the new device is safe and provides equivalent performance to the primary predicate device in terms of safety and performance. The most common side effects reported for both devices are headache and/or pain at stimulation site.
In addition, a small pilot trial using the new device also demonstrated a clinically and statistically significant effect of treatment of OCD. Despite the low number of subjects, this trial supports the performance of the new device as an adjunct for treatment of OCD, even though the protocol was utilizing lower frequency of stimulation, that is 10 Hz compared to 20 Hz.

Taken together, the literature demonstrates that the new device can be used effectively and routinely for determining Leg MT, and that the treatment modulates brain activity locally in the DMPFC and strongly suggests also distal brain areas, through downstream activation of long-range networks. Though MDD and OCD are two distinct psychiatric disorders, they share some common underlying deficits in brain networks. So, though most of the research using the new device has investigated treatment of MDD, the data can support the use of the new device as an adjunct for treatment of OCD in terms of safety and given that the treatments have been performed targeting the same cortical area, DMPFC bilaterally, in a substantially equivalent way to the primary predicate device.

Finally, the clinical data for the new device essentially supports the modelled e-fields presented above, and treatment with the new device is as safe as treatment with the primary predicate device. There is no reason to suspect increased risk for unwanted or severe side effects. Moreover, clinical data shows the new device’s ability to deliver effective treatment of the DMPFC and potentially affecting deeper cortical brain areas. We therefore conclude that the new device is substantially equivalent to the primary predicate device in terms of performance, effectiveness and safety.

Substantial equivalence:
The MagVenture TMS Therapy system - for adjunctive treatment of OCD is substantially equivalent to the primary predicate device, the Brainsway DTMS system HAC – H7 coil. The MagVenture TMS Therapy system - for treatment of OCD and the primary predicate device have identical indication for use, and identical treatment parameters as well as treatment target. The magnetic field properties of the Cool D-B80 is substantially equivalent to the primary predicate device, the Brainsway DTMS HAC – H7 coil (DEN170078, K183303).
All components of the new device, except the Cool D-B80 coil, are identical to those of the predicate device. These have all previously obtained FDA clearance for treatment of major depressive disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode (K150641, K171967 and K173620).
The new coil, Cool D-B80 is also identical to that of the predicate devices, in terms of materials, design elements, liquid cooling and biocompatibility.

The treatment protocol is identical to that of the primary predicate device, and applies transcranial magnetic stimulation (TMS) at an intensity of 100% of Leg Motor Threshold (MT) as repetitive pulse trains at a frequency of 20 Hz delivered as brief rapidly alternating magnetic fields to induce electrical currents over the dorsomedial prefrontal cortex (DMPFC). All labelling claims related to effectiveness and safety are based on the literature describing the pivotal clinical trial results of the primary predicate device for the proposed intended use.
Both the MagVenture TMS Therapy system - for adjunctive treatment of OCD and the predicate devices consist of the same components, that is a TMS stimulator with software, an articulated arm for positioning of the treatment coil. The operational procedures including system setup, patient preparations, motor threshold determination and coil positioning are substantially equivalent.

Area	New Device	Predicate Device	Primary Predicate Device
	MagVenture TMS Therapy system – for treatment of OCD **Tonica Elektronik A/S, Denmark**	**MagVenture TMS Therapy system** **(K150641, K171481, K171967, K172667, K173620)** **Tonica Elektronik A/S, Denmark**	**Brainsway Deep Transcranial magnetic stimulation (DTMS) System and HAC – H7 coil (DEN170078, K183303)** **Brainsway Ltd., Israel**
Indications for use	The MagVenture TMS Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD)	NA	The Brainsway DTMS system is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD)
Energy Delivered and Performance	<u>Treatment parameters:</u> Intensity: 100% of Leg MT (Leg Motor Threshold) Repetition rate: 20Hz Train duration: 2 sec Inter-train-Interval: 20 secs Number of trains: 50 Numbers of pulses: 2000 Total duration: 18.0 min.	NA	<u>Treatment parameters:</u> Intensity: 100% of Leg MT (Leg Motor Threshold) Repetition rate: 20Hz Train duration: 2 sec Inter-train-Interval: 20 secs Number of trains: 50 Numbers of pulses: 2000 Total duration: 18.3 min.
	<u>Treatment area:</u> Area of brain to be stimulated: Dorsomedial Prefrontal Cortex	NA	<u>Treatment area:</u> Area of brain to be stimulated: Dorsomedial Prefrontal Cortex
	<u>Output Stimulation Parameters:</u> Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units Range: 0 - 1.9 SMT Waveform: Biphasic	<u>Output Stimulation Parameters:</u> Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units Range: 0 - 1.7 SMT Waveform: Biphasic	<u>Output Stimulation Parameters:</u> Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units Range: 0.6- 1.4 SMT Waveform: Biphasic
Design	<u>The system consists of</u>: 1. Mobile console 2. System software with GUI 3. Treatment chair* 4. Head support system* 5. Coil positioning system 6. Same Coil for both MT and treatment 7. Coil Fixture 8. Data Management System **optional*	<u>The system consists of</u>: 1. Mobile console 2. System software with GUI 3. Treatment chair* 4. Head support system* 5. Coil positioning system 6. Coil for MT and coil for treatment 7. Coil Fixture 8. Data Management System **optional*	<u>The system consists of</u>: 1. Mobile console 2. System software 3. Treatment chair* 4. Helmet with Coil for MT 5. and for treatment 6. Coil positioning system
Coil	Double-cone coil Air core	Figure-of-eight coils (butterfly coil) Air core	Double-cone coil contained in a helmet. Air core

Cooling	Liquid cooled Used for both MT determination and treatment.	Liquid cooled Used for both MT determination and treatment.	Air cooled. Used for both MT determination and treatment.
Standards	Company complies with EN ISO 13485:2016.	Company complies with EN ISO 13485:2016.	Company complies with ISO 13485:2016.
Electrical safety	Complies with IEC60601-1 v. 3.1, and IEC60601-1-2.	Complies with IEC60601-1 v. 3.1, and IEC60601-1-2.	

For a more comprehensive comparison of devices please refer to section 10, Device Description and section 12, Substantial Equivalence Comparison.

Conclusion:

The new device, MagVenture TMS Therapy system – for adjunctive treatment of OCD, is identical to the predicate device, MagVenture TMS Therapy system, except for the treatment coil, Cool D-B80, which has not previously been cleared by the FDA. All other components of the new device have previously been cleared by the FDA, most recently in 2018 (K173620).

The indication for use, the target population, the TMS treatment protocol and the treatment position are all identical for the MagVenture TMS Therapy system and the primary predicate device, Brainsway DTMS System (DEN170078). The treatment parameters proposed for the new device are identical to those recommended by the primary predicate device. Clinical evidence pertaining to the new device demonstrates that the treatment is safe, well-tolerated and effective. The new device is substantially equivalent to the primary predicate device in terms of performance, safety and effectiveness.

The new coil is identical to the predicate coils, Cool-B70 and Cool-B65, in terms of design parameters, such as materials, biocompatibility, liquid cooling and pulse width. The new coil is substantially equivalent to the primary predicate device, Brainsway DTMS HAC – H7 coil in terms of magnetic properties and magnetic spatial distribution. The two coils are both so-called double cone coils, which contain two individual, non-overlapping magnetic coils that allow for a broader and more deep stimulation of the cortex. E-field modelling of the new device compared to the primary predicate device demonstrates that the magnetic field properties and the depth penetration of the two devices in the human cortex are substantially equivalent.
The clinical data submitted with this 510(k), helps support the performance and safety of the new device and shows that also the side effect profile is substantially equivalent to that of the primary predicate.

The reliability of the positioning method used by the new device 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 devices.

The MagVenture TMS Therapy system – for adjunctive treatment of OCD does not introduce any new safety considerations in comparison to the predicate devices.

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 equivalence of the MagVenture TMS Therapy system – for adjunctive treatment of OCD to the predicate devices, Brainsway DTMS System (DEN170078; primary predicate), and the MagVenture TMS Therapy system (K150641, K171481, K171967, K172667, K173620).

Reference List

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3. Dunlop K, Woodside B, Olmsted M, Colton P, Giacobbe P, Downar J. Reductions in Cortico-Striatal Hyperconnectivity Accompany Successful Treatment of Obsessive-Compulsive Disorder with Dorsomedial Prefrontal rTMS. Neuropsychopharmacology. 2016;41(5):1395-403.

4. Miron JP, Feffer K, Cash RFH, Derakhshan D, Kim JMS, Fettes P, et al. Safety, tolerability and effectiveness of a novel 20 Hz rTMS protocol targeting dorsomedial prefrontal cortex in major depression: An open-label case series. Brain Stimul. 2019.

5. Schulze L, Feffer K, Lozano C, Giacobbe P, Daskalakis ZJ, Blumberger DM, et al. Number of pulses or number of sessions? An open-label study of trajectories of improvement for once-vs. twice-daily dorsomedial prefrontal rTMS in major depression. Brain Stimul. 2018;11(2):327-36.

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refractory major depressive disorder: A three-arm, blinded, randomized controlled trial. Brain Stimul. 2019.

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10. Bakker N, Shahab S, Giacobbe P, Blumberger DM, Daskalakis ZJ, Kennedy SH, et al. rTMS of the dorsomedial prefrontal cortex for major depression: safety, tolerability, effectiveness, and outcome predictors for 10 Hz versus intermittent theta-burst stimulation. Brain Stimul. 2015;8(2):208-15.