December 29, 2023

NeuroQore, Inc.
℅ Barry Ashar
President
Makromed, Inc.
88 Stiles Road
Salem, New Hampshire 03079

Re: K232688
Trade/Device Name: NQ TMS for MDD (NQv1-MU-01)
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: November 29, 2023
Received: November 30, 2023

Dear Barry Ashar:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2023.12.29 14:36:47 -05'00'

for Pamela Scott, MS
Assistant Director
DHT5B: Division of Neuromodulation and Rehabilitation 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232688

Device Name

NQ TMS for MDD (NQv1-MU-01)

Indications for Use *(Describe)*

The NQ TMS for MDD 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) #: K232688	510(k) Summary	Prepared on: 2023-11-29

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NQ TMS for MDD (NQv1-MU-01)
Common Name	Repetitive transcranial magnetic stimulation system
Classification Name	Transcranial Magnetic Stimulator
Regulation Number	882.5805
Product Code	OBP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K171481	MagVita TMS Therapy System	OBP
K150641	MagVita TMS Therapy System	OBP

Device Description Summary

21 CFR 807.92(a)(4)

The NeuroQoreTMS System (NQ TMS for MDD) enables direct non-invasive activation of brain structures. TMS is a non-invasive technique used to apply brief magnetic pulses to the brain. The pulses are administered by passing high currents through an electromagnetic coil placed adjacent to a patient's scalp. The pulses induce an electric field in the underlying brain tissue. When the induced field is above a certain threshold, and is directed in an appropriate orientation relative to the brain's neuronal pathways, localized axonal depolarizations are produced, thus activating neurons in the targeted brain structure.

The NeuroQoreTMS System is composed of the following main components:
- TMS Stimulator and Cooling Unit
- Treatment Coil (Applicator) (Figure-of-eight)
- Coil Arm (Applicator Arm)
- Treatment Cap

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The NQ TMS for MDD 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device of this 510(k) submission has the exact same Indication for Use as that of the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

Introduction
The proposed device, the NQ TMS for MDD, and the predicate device, MagVita TMS Therapy System (K171481, K150641) are computerized electromechanical medical devices that produce and deliver non-invasive, repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the prefrontal cortex for the treatment of Major Depressive Disorder.

Design
The design of the NQ TMS for MDD is similar to that of the MagVita TMS Therapy System, as both systems are based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency. Both systems use the same mechanism of action, i.e., an electromechanical instrument that produces and delivers brief duration, rapidly alternating (pulsed) magnetic fields to induce electrical currents in localized regions of the prefrontal cortex. The coils used in both systems for generating the magnetic field use the same transducer design (figure-of-eight).

Operational Characteristics
For both the subject and the predicate device, their basic operational procedures including system setup, patient preparations, motor threshold determination, coil positioning and treatment with predefined treatment stimulation parameters are essentially the same. Both devices use the following 19-minutes MDD treatment protocol:

- Magnetic Field Intensity: 120% of the MT
- Frequency: 10 Hz
- Train Duration: 4 seconds
- Inter-train Interval: 11 seconds
- Number of Trains: 75
- Magnetic Pulses per Session: 3000
- Treatment Session Duration: 18.8 minutes
- Sessions/week: 5
- Treatment Schedule: 5 daily sessions for 6 weeks
- Area of Brain to be Stimulated: Frontal Cortex

Technological Characteristics
The NQ TMS for MDD and the predicate device have the same components consisting of TMS stimulator with software, electromagnetic coil and a flexible arm for positioning of the treatment coil.

All the necessary electromagnetic compatibility and electrical safety tests for the NQ TMS for MDD were performed. The results demonstrate that it is in compliance with both the standards IEC 60601-1-2 and IEC 60601-1; therefore, it is as safe as the predicate device.

The tested magnetic properties of the NQ TMS for MDD and the predicate device are substantial equivalent for the coils.

The reliability of the positioning method used by the NQ TMS for MDD 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 NQ TMS for MDD is at least as effective as the method employed by the predicate device.

The basic software capabilities related to treatment administration in the NQ TMS for MDD are the same as those in the predicate device.

Criteria	NeuroQore rTMS (Subject Device)	MagVita TMS Therapy System (K171481) (Predicate Device)	Equivalence Comments
Intended Use (Indication for Use)	The NQ TMS for MDD 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.	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.	Identical Indication for Use
Recommended Standard Treatment			
Magnetic Field Intensity	120% of the MT	120% of the MT	Identical recommended treatment parameters. The subject and predicate device provide the same treatment option of 18.8-minutes treatment duration, using 11 sec inter-train intervals. The subject device does not provide the legacy 37-minutes treatment using 26 sec inter-train intervals, which has been superseded in the past few years by the
Frequency	10 Hz	10 Hz	
Train duration	4 sec	4 sec	
Inter-train interval	11 sec	11-26 sec	
Number of trains	75	75	
Magnetic Pulses per Session	3000	3000	
Treatment Session Duration	18.8 min	18.8-37.0 min	
Sessions/week	5	5	

Criteria	NeuroQore rTMS (Subject Device)	MagVita TMS Therapy System (K171481) (Predicate Device)	Equivalence Comments
Treatment Schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	18.8 minutes treatment prevailing in the current clinical practices.
Area of brain to be stimulated	Frontal Cortex	Frontal Cortex	
Coils			
Coils	NQv1-AC-01	C-B65	N/A
Configuration	Figure-of-eight coil	Figure-of-eight coil	Same figure-of-eight configuration in both coils.
Core material	Air core	Air core	Same core material design.
Cooling	Liquid cooling	Liquid cooling	Same liquid-cooling mechanism in both coils.
Coil parameters	Inner diameter - 25 mm Outer diameter - 100 mm N = 2 wings x 1 layers x 15 turns	Inner diameter - 35 mm Outer diameter - 75 mm N = 2 wings x 2 layers x 5 turns	Equivalent, with no additional concerns for safety and effectiveness. See Note A for equivalence explanation of coil parameters such as dimensions and windings.
Machine Output Parameters			
Amplitude in Standard Motor	0% Intensity Setting → 0 SMT	0% Intensity Setting → 0 SMT	Equivalent, with no additional concerns for safety and effectiveness.

Criteria	NeuroQore rTMS (Subject Device)	MagVita TMS Therapy System (K171481) (Predicate Device)	Equivalence Comments
Threshold (SMT) units	44.3% Intensity Setting → 1.0 SMT 100% Intensity Setting → 2.7 SMT	37.8% Intensity Setting → 1.0 SMT 100% Intensity Setting → 3.0 SMT	See Note B for equivalence explanation of Intensity/Amplitude.
Waveform	Biphasic triangular	Biphasic sinusoid	Equivalent, with no additional concerns for safety and effectiveness. See Note C for equivalence explanation of Waveform.
Active pulse width (µs)	300	290	Equivalent, with no additional concerns for safety and effectiveness. See Note D for equivalence explanation of Pulse Width and Amplitude.
Pulse amplitude (V)	38.56	39.12	
Max magnetic field strength 2 cm from coil (T)	At 30% Intensity: 0.088 At 50% Intensity: 0.229 At 70% Intensity: 0.332 At 100% Intensity: 0.490	At 30% Intensity: 0.126 At 50% Intensity: 0.246 At 70% Intensity: 0.326 At 100% Intensity: 0.510	Equivalent, with no additional concerns for safety and effectiveness. See Note E for equivalence explanation of Max magnetic field strength.

Criteria	NeuroQore rTMS (Subject Device)	MagVita TMS Therapy System (K171481) (Predicate Device)	Equivalence Comments
Max initial dB/dt (kT/s) near the coil surface (z = 0 cm)	15.28	15.51	Equivalent, with no additional concerns for safety and effectiveness. See Note F for equivalence explanation of dB/dt.
Max initial dB/dt (kT/s) 2 cm from coil surface (z = 2 cm)	5.30	5.59	
Coil Temperature at Max Intensity The system will be automatically disabled when the coil temperature exceeds:	41 °C (106 °F)	41 °C (106 °F)	Regardless of the intensity setting (at Maximum output or otherwise), both the subject and predicate device have a coil temperature safety feature that shuts down the system when the threshold temperature is reached.
Frequency range (Hz)	0.1 to 20	0.1 to 30 or 0.1 to 100, depending on model	The differences in these parameters are simply the differences in the overall capabilities of these machines. These capabilities encompass the recommended treatment
Pulse train duration range (s)	1 to 4	Rep Rate: 0.1 ...100Hz Pulses in Train: 1,2,3,4 ... 1000 Train duration = Pulses in Train / Rep Rate	

Criteria	NeuroQore rTMS (Subject Device)	MagVita TMS Therapy System (K171481) (Predicate Device)	Equivalence Comments
Inter-train interval range (s)	1 to 11	1 to 120	parameters for MDD listed above. In other words, these variations among different manufacturers' models do not impact their ability to deliver the treatment parameters recommended for MDD. Both machines use identical treatment parameters.
Maximum trains per session	75	500	
Maximum number of pulses per session	3000	500,000 = 1,000 (pulses max per train) x 500 (trains max per session)	
Standards			
Electrical safety	Complies with IEC 60601-1， IEC 60601-1-2.	Complies with IEC 60601-1, IEC 60601-1-1 and IEC 60601-1-2.	N/A
ISO Standards met	Company complies with ISO 13485:2016. ISO14971	Company complies with ISO 13485:2012.	N/A

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following special control is applicable to the subject device (Product Code: OBP) of this 510(k) submission:
"Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems."

The following performance tests specified in this guidance document were performed and the results were compared for a determination of substantial equivalence between the subject device (NQ TMS System) and the predicate device (MagVita TMS System):
Electric Field:
a. SMT Comparison
b. Electrical Field Strength Decay over z-axis distance from coil center (in the direction of head center)

Magnetic Field:
a. Output Waveform for pulse width and amplitude
b. Magnetic Field Strength Linearity as a function of machine intensity setting
c. Magnetic Field Spatial Distribution
d. Magnetic Field Gradient (dB/dt)

Electrical/Mechanical/Thermal Safety (IEC 60601-1)
Electromagnetic Compatibility (IEC 60601-1-2)
Biocompatibility (ISO 10993-1)
Software Validation (FDA Guidance)

Conclusion Statement
The subject device (NQ TMS for MDD System) and the predicate device (MagVita TMS System) have identical intended use/indication for use, target population, treatment procedure, treatment position and all recommended standard treatment protocol parameters (intensity, frequency, number of pulses in a train, number of trains in a session, number of treatment sessions).
Both, the proposed device and predicate device share the same Figure-of-eight coil design. The tested electric field and magnetic field properties of the NQ TMS for MDD and the predicate devices are substantial equivalent for the coils.
The reliability of the positioning method used by the NQ TMS for MDD 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 NQ TMS for MDD is the same as the method employed by the predicate devices.
The NQ TMS System does not introduce any new safety considerations in comparison to the predicate device. All other identified differences between the proposed device and the predicates are minor and without any known impact on safety or efficacy.
Based on the information and supporting documentation provided in the premarket notification, the NQ TMS for MDD is substantially equivalent to the cited predicate device. Testing demonstrates that the NQ TMS for MDD fulfills prospectively defined design and performance specifications.