Friday, August 14, 2026

Brain Ultimate, Inc.
℅ Barry Ashar
President
Makromed, Inc.
88 Stiles Rd.
Salem, New Hampshire 03079

Re: K261228
Trade/Device Name: QuickVision Ultimate rTMS
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP, SGE
Dated: April 14, 2026
Received: April 15, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

PAMELA D. SCOTT -S

Pamela D. 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261228

Please provide the device trade name(s).

QuickVision Ultimate rTMS

Please provide your Indications for Use below.

The QuickVision Ultimate rTMS is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medications in the current episode. The QuickVision Ultimate rTMS includes a neuronavigation system indicated to provide navigation and location support for placement of the TMS coil on the skull in relation to a prior acquired MRI image.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(K) Summary

This summary is provided to support the 510(k) pre-market notification for the QuickVision Ultimate rTMS.

Date Summary Prepared: August 14, 2026

CONTACT DETAILS

Applicant Name: Brain Ultimate, Inc.

Applicant Contact: Mr. Frank Ge, Frank.Ge@brainultimate.com

Applicant Address: 5910 Shiloh Road East Alpharetta GA 30005 United States

Correspondent Name: Makromed, Inc.

Correspondent Contact: Mr. Barry Ashar, bashar@makromed.com

Correspondent Address: 88 Stiles Road Salem NH 03079 United States

DEVICE NAME

Device Trade Name: QuickVision Ultimate rTMS

Common Name: Repetitive transcranial magnetic stimulation system

Classification Name: Repetitive transcranial magnetic stimulation system

Regulation Number: 882.5805

Product Code(s): OBP, SGE

PREDICATE DEVICES

Primary Predicate: K243460, Ultimate rTMS, OBP

Secondary Predicate: K210109, visor2 system, HAW

PRODUCT DESCRIPTION

The QuickVision Ultimate rTMS is a repetitive transcranial magnetic stimulation (rTMS) system coupled with a neuronavigation system. This computerized medical device produces 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. Its neuronavigation feature is used to aid 3D navigation for positioning of TMS coils over preselected brain regions based on data from MRI measurements or scalp landmarks.

It can be used in patient care institutions, diagnostics centers, neurosurgical hospitals and experimental laboratories of research institutions.

The Ultimate rTMS principle of operation is based on the discharge of high voltage capacitor through stimulation coil; the pulsed magnetic field generated by the discharge current penetrates through neuromuscular tissues nearby to induce electrical currents in cortical neurons. The Neuronavigator uses position data of the patient's head and the TMS coil acquired by an optical tracking system for display and navigation. The real-time display of the position of the TMS coil in the displayed MR data set provides visual support for navigation.

Area of the brain to be simulated for MDD treatment is Left Dorsolateral Prefrontal Cortex.

INDICATION FOR USE

The QuickVision Ultimate rTMS is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medications in the current episode. The QuickVision Ultimate rTMS includes a neuronavigation system indicated to provide navigation and location support for placement of the TMS coil on the skull in relation to a prior acquired MRI image.

INDICATIONS FOR USE COMPARISON

The subject device of this 510(k) submission has the exact same Indication for Use as that of the predicate devices put together (TMS + Neuronavigation).

TECHNOLOGICAL COMPARISON

Introduction

The subject device, the QuickVision Ultimate rTMS, and the primary predicate device, Ultimate rTMS (K243460) are used for the treatment of Major Depressive Disorder in adult patients. They are both 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. Both devices have identical intended use / indication for use, identical hardware components, identical treatment target and use identical treatment parameters of 19-minutes, 37-minutes and iTBS protocols.

The subject device, the QuickVision Ultimate rTMS, and the secondary predicate device, visor2 System (K210109) are used to aid 3D navigation for positioning of Transcranial Magnetic Stimulation (TMS) coils over preselected brain regions based on data from MRI measurements or scalp landmarks. The subject device is a combination of a TMS System and a neuronavigation system, where as the secondary predicate device is a stand-alone neuronavigation system. The TMS part of the subject device is identical to the primary predicate device.

The subject device is the exact same as the primary predicate device with the neuronavigation feature added to it. The added neuronavigation feature is similar to the one provided by the secondary predicate device.

Design

The TMS part of the design of the subject device is the exact same as that of the primary predicate device for applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency. Both 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. Both use the exact same TMS coils of figure-of-eight transducer design.

The neuronavigation part of the design of the subject device is very similar to that of the secondary predicate device as their TMS coil positioning principle is based on anatomy (MRI picture) and indirect targeting of treatment target through measured distance and direction using optical stereotactic navigation. Both systems use the same fundamental technology for locating TMS coil location with regard to prior acquired MRI images, consisting of Infrared locators and 3D tracking infrared camera technology for land-marking to facial and skull features using tracking tools.

Operational Characteristics

For the subject device and the primary predicate device, their basic operational procedures for TMS treatment, including system setup, patient preparations, motor threshold determination, coil positioning and treatment with predefined treatment stimulation parameters are exactly the same.

For the subject device and the secondary predicate device, their basic operational procedures for neuronavigation, including system setup, patient preparations, and coil position tracking are the same as they both use the exact same 3D tracking system (Polaris from Northern Digital, Inc.) and tracking tools such as patient marker, coil marker and pointer tool.

Technological Characteristics

Both the subject and primary predicate devices have similar components consisting of TMS stimulator with software, electromagnetic coil and a flexible arm for positioning of the treatment coil. They both use the exact same figure-of-eight coils, the exact same treatment protocols (37-min, 19-min and iTBS) and the exact same treatment parameters (frequency and intensity). The coil positioning method used by the primary predicate device is based on the direct relationship of the underlying cortical brain anatomy to the patient's scalp. The subject device can use this exact same positioning method, and also offers more accurate neuronavigation-based coil positioning method similar to the one in the secondary predicate device.

Both the subject and secondary predicate devices employ optical stereotactic navigation technology and use the same or very similar components consisting of the Polaris 3D tracking system and tracking tools such as patient marker, coil marker and pointer tool. They both import MRI images in DICOM format, perform semi-automated image segmentation of skin and brain from patient MRI, and generate accurate 3D model of the patient head. They provide 3D visual guidance for positioning of the TMS coil for accurate target selection for TMS stimulation.

Non-clinical Performance Characteristics

1. Electrical/mechanical/thermal safety and electromagnetic compatibility of both the subject and predicate devices are in compliance with the following standards:

- IEC 60601-1:2005/(R)2012
- IEC 60601-1-2:2014

2. Patient caps are the only accessory of the subject device that comes in contact with the patient's intact skin for an aggregated duration of less than 24 hours, over a period of 30 days of treatment days. As they are made of commonly used textile materials, they are exempt from ISO 10993-1:2018 Biocompatibility testing per FDA's Guidance Document 'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"', dated September 8, 2023.

3. The characteristics of the electric and magnetic fields generated by the subject device's coils (BY90A, BF90A, and BY90B), including linearity of output, biphasic sinusoidal waveform, pulse width and intensity, magnetic field spatial distribution and magnetic field strength gradient, are identical to

that of the primary predicate device. This is because the subject device is the same as the primary predicate device with a neuronavigation feature added to it, which has no impact on the electric and magnetic fields generated by the device.

4. The subject device meets the same requirement as the primary predicate device that the actual individual stimuli of a theta burst are of equal intensity to ensure that a constant dose of stimuli is delivered during iTBS treatment (maximum 1% drop in machine output among the three stimuli in a burst). This is because the subject device is the same as the primary predicate device with a neuronavigation feature added to it, which has no impact on the stimulation intensity generated by the device.

5. The subject device's tracking system accuracy is the same as that of the secondary predicate device as both use the exact same commercially available tracking system from a third party (Polaris from Northern Digital, Inc.).

Conclusion

The subject device, QuickVision Ultimate rTMS, is the same as the primary predicate device (Ultimate rTMS, K243460) with a neuronavigation feature added to it that is equivalent to the secondary predicate device (Visor2, K210109).

The subject device does not introduce any new safety considerations in comparison to the primary or secondary predicate devices. All other identified differences between the subject device and the predicate devices are minor and without any known impact on safety or efficacy.

Table 12-1. Side-by-Side Comparison of the Subject and Primary Predicate Device (for comparison of TMS-related features and performance)

Criteria	(Subject Device) QuickVision Ultimate rTMS	(Primary Predicate) Ultimate rTMS (K243460)	Equivalence Comments
Product Classification	OBP / 21 CFR 882.5805 Class II device	OBP / 21 CFR 882.5805 Class II device	Identical
Magnetic Field Intensity	120% of the MT (iTBS, 19/37 mins protocols)	120% of the MT (iTBS, 19/37 mins protocols)	Identical treatment protocols and parameters.
Repetition Rate	50 Hz / 10 Hz (iTBS, 19/37 mins protocols)	50 Hz / 10 Hz (iTBS, 19/37 mins protocols)	
Train duration	2 sec / 4 sec (iTBS, 19/37 mins protocols)	2 sec / 4 sec (iTBS, 19/37 mins protocols)	
Inter-train interval	8 sec / 11-26 sec (iTBS, 19/37 mins protocols)	8 sec / 11-26 sec (iTBS, 19/37 mins protocols)	
iTBS Burst	Burst Pulses: 3 No. of Bursts: 200 Inter-pulse: 20 msec	Burst Pulses: 3 No. of Bursts: 200 Inter-pulse: 20 msec	
Number of trains	20 / 75 (iTBS, 19/37 mins protocols)	20 / 75 (iTBS, 19/37 mins protocols)	
Magnetic Pulses per Session	600 / 3000 (iTBS, 19/37 mins protocols)	600 / 3000 (iTBS, 19/37 mins protocols)	
Treatment Session Duration	3 min 12 sec / 19/37 min (iTBS, 19/37 mins protocols)	3 min 12 sec / 19/37 min (iTBS, 19/37 mins protocols)	

Criteria	(Subject Device) QuickVision Ultimate rTMS	(Primary Predicate) Ultimate rTMS (K243460)	Equivalence Comments
Treatment Schedule	5 Sessions/Week for 6 Weeks	5 Sessions/Week for 6 Weeks	
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	
Coils	BY90A BF90A BY90B	BY90A BF90A BY90B	Identical coils.
Configuration	BY90A： Figure-of-eight coil BF90A： Figure-of-eight coil BY90B： Figure-of-eight coil-With angle 120°	BY90A： Figure-of-eight coil BF90A： Figure-of-eight coil BY90B： Figure-of-eight coil-With angle 120°	
Core material	Air core	Air core	
Cooling	BY90A:Liquid cooling	BY90A:Liquid cooling	
	BF90A:Forced Air cooling	BF90A:Forced Air cooling	
	BY90B:Liquid cooling	BY90B:Liquid cooling	
Coil parameters	BY90A Inner diameter - 34 mm Outer diameter - 85 mm N = 2 wings x 2 layers x 5 turns	BY90A Inner diameter - 34 mm Outer diameter - 85 mm N = 2 wings x 2 layers x 5 turns	
	BF90A Inner diameter - 34 mm Outer diameter - 85 mm N = 2 wings x 2 layers x 5 turns	BF90A Inner diameter - 34 mm Outer diameter - 85 mm N = 2 wings x 2 layers x 5 turns	

Criteria	(Subject Device) QuickVision Ultimate rTMS	(Primary Predicate) Ultimate rTMS (K243460)	Equivalence Comments
	BY90B Inner diameter - 30 mm Outer diameter -90 mm N = 2 wings x 2 layers x 6 turns	BY90B Inner diameter - 30 mm Outer diameter -90 mm N = 2 wings x 2 layers x 6 turns	
Amplitude in Standard Motor Threshold (SMT) units	0 – 2.4 41% Intensity Setting → 1 SMT	0 – 2.4 41% Intensity Setting → 1 SMT	Identical electric and magnetic field characteristics.
Waveform	Biphasic sinusoid	Biphasic sinusoid	
Active pulse width (μs)	320	320	
Pulse amplitude (V)	BY90A: 1.35 BF90A: 1.26 BY90B: 1.22	BY90A: 1.35 BF90A: 1.26 BY90B: 1.22	
Max magnetic field strength 2 cm from coil (T)	At 25% Intensity: BY90A: 0.172 BF90A: 0.182 BY90B: 0.117 At 50% Intensity: BY90A: 0.291 BF90A: 0.287 BY90B: 0.244 At 75% Intensity: BY90A: 0.403 BF90A: 0.395 BY90B: 0.369 At 100% Intensity:	At 25% Intensity: BY90A: 0.172 BF90A: 0.182 BY90B: 0.117 At 50% Intensity: BY90A: 0.291 BF90A: 0.287 BY90B: 0.244 At 75% Intensity: BY90A: 0.403 BF90A: 0.395 BY90B: 0.369 At 100% Intensity:	

Criteria	(Subject Device) QuickVision Ultimate rTMS	(Primary Predicate) Ultimate rTMS (K243460)	Equivalence Comments
	BY90A: 0.498 BF90A: 0.494 BY90B: 0.481	BY90A: 0.498 BF90A: 0.494 BY90B: 0.481	
Max initial dB/dt (kT/s) near the coil surface (z = 0 cm)	BY90A: 13.44 BF90A: 13.76 BY90B: 12.10	BY90A: 13.44 BF90A: 13.76 BY90B: 12.10	Identical electric and magnetic field characteristics.
Max initial dB/dt (kT/s) 2 cm from coil surface (z = 2 cm)	BY90A: 3.59 BF90A: 4.27 BY90B: 6.78	BY90A: 3.59 BF90A: 4.27 BY90B: 6.78	
Output Intensity Stability among Pulses in a Burst (Max Change %)	BY90A: 0.563 BF90A: 0.580 BY90B: 0.679	BY90A: 0.563 BF90A: 0.580 BY90B: 0.679	
The system will automatically be disabled when the coil temperature exceeds:	40 °C (104 °F)	40 °C (104 °F)	Identical coil temperature control and alarm.

Criteria	(Subject Device) QuickVision Ultimate rTMS	(Primary Predicate) Ultimate rTMS (K243460)	Equivalence Comments
Frequency range (Hz)	0.1 - 100	0.1 - 100	Identical system specifications.
Pulse train duration range (s)	Rep Rate: 0.1 ...100Hz Pulses in Train: 1,2,3,4 ... 2000 Train duration = Pulses in Train / Rep Rate	Rep Rate: 0.1 ...100Hz Pulses in Train: 1,2,3,4 ... 2000 Train duration = Pulses in Train / Rep Rate	
Inter-train interval range (s)	0 - 60	0 - 60	
Maximum trains per session	250	250	
Maximum number of pulses per session	5000 (Pluses In Train:20 *Maximun Trains:250 =Maximun Number:5000)	5000 (Pluses In Train:20 *Maximun Trains:250 =Maximun Number:5000)	
Electrical safety	Complies with IEC 60601-1，IEC 60601-1-2.	Complies with IEC 60601-1，IEC 60601-1-2.	Identical compliance with external standards.
ISO Standards met	Company complies with ISO 13485:2016. ISO14971	Company complies with ISO 13485:2016. ISO14971	

Table 12-2. Side-by-Side Comparison of the Subject and Secondary Predicate Device (for comparison of neuronavigation-related features and performance)

Criteria	(Subject Device) QuickVision Ultimate rTMS	(Secondary Predicate) Visor2 (K210109)	Equivalence Comments
Product Classification	SGE / 21 CFR 882.4560 Class II device	HAW / 21 CFR 882.4560 Class II device	Equivalent (Neuronavigation for TMS has been cleared under both SGE and HAW)
TMS Coil Position Principle	Based on anatomy (MRI picture) and indirect targeting of treatment target through measured distance and direction using optical stereotactic navigation.	Based on anatomy (MRI picture) and indirect targeting of treatment target through measured distance and direction using optical stereotactic navigation.	Identical
Fundamental technology for locating TMS coil location with regard to prior acquired MRI images	Infrared locators and 3D tracking infrared camera technology for land-marking to facial and skull features using tracking tools.	Infrared locators and 3D tracking infrared camera technology for land-marking to facial and skull features using tracking tools.	Identical
Compatible TMS Coils	Commercially available Brain Ultimate coils cleared for TMS use: BY90A BY90B BF90A	Commercially available TMS coils from several manufacturers.	Equivalent
Neuronavigation Components	3D Tracking System Patient Marker Coil Marker Pointer Tool Computer Software	3D Tracking subsystem (Stereotactic camera positioning system), Calibration board, Reference tracking tool, Pointer tool, Coil tracker, Computer, Software, Cart	Equivalent

Criteria	(Subject Device) QuickVision Ultimate rTMS	(Secondary Predicate) Visor2 (K210109)	Equivalence Comments
	Cart		
3D Tracking System	Commercially available optical stereotactic Polaris tracking system from Northern Digital Inc.	Commercially available optical stereotactic Polaris tracking system from Northern Digital Inc.	Identical
Tracking System Accuracy	0.25 mm RMS	0.25 mm RMS	Identical
System Accuracy	4 mm	4 mm	Identical
Scanner Interface	Import of MRI images in DICOM format. Import of fMRI/PET images. Mapping results exported as CSV text file and DICOM images with voxel coloring according to motor response amplitudes and language mapping classifications.	Import of MRI images in DICOM format. Import of fMRI/PET images. Mapping results exported as CSV text file and DICOM images with voxel coloring according to motor response amplitudes and language mapping classifications.	Equivalent
MRI Features	• tMRI/MRI import • MRI based head modeling • efield visualization	• tMRI/MRI import • MRI based head modeling • efield visualization	Equivalent
DICOM conformance	Yes	Yes	Equivalent
Brain Segmentation	Semi-automated image segmentation of skin and brain from patient MRI.	Semi-automated image segmentation of skin and brain from patient MRI.	Equivalent

Criteria	(Subject Device) QuickVision Ultimate rTMS	(Secondary Predicate) Visor2 (K210109)	Equivalence Comments
Head Model	Generation of accurate 3-D model of the patient's head.	Generation of accurate 3-D model of the patient's head.	Equivalent
Planning Features	Coil targets to deliver TMS to specific area; includes visibility, location and description.	Coil targets to deliver TMS to specific area; includes visibility, location and description.	Equivalent
2D and 3D Viewing	Axial, coronal, sagittal slices through configurable cut planes in 3D scene.	Axial, coronal, sagittal slices through configurable cut planes in 3D scene.	Equivalent
Registration Feature	Crosshairs to register specific MRI landmarks, pointer tool and head tracker; validation tests to determine inaccuracies.	Crosshairs to register specific MRI landmarks, pointer tool and head tracker; validation tests to determine inaccuracies.	Equivalent
Electrical Safety	Complies with IEC 60601-1	Complies with IEC 60601-1	Equivalent
EMC	Complies with IEC 60601-1-2	Complies with IEC 60601-1-2	Equivalent

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY

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 their results for the subject device are identical to the primary predicate device of our own (K243460), as there is no difference between them in their TMS features and design, including the coils used:

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)

Also, the "Intensity Variation of Pulses within a Burst" not specified in the guidance document but essential for iTBS protocol was performed. The results for the subject device are identical to the primary predicate device of our own (K243460), as there is no difference between them in their TMS features and design.

An additional test related to the neuronavigation feature, linear and angular accuracy of tracking, was performed and its report is attached in this 510(k).

CONCLUSION STATEMENT

The subject device and the predicate devices have identical intended use/indication for use, target population, treatment procedure, treatment position and all recommended standard treatment protocol parameters.

The subject device is the exact same as the primary predicate device with the neuronavigation feature added to it. The added neuronavigation feature is similar to the one provided by the secondary predicate device.

Bench-top testing results for the subject device for its TMS functionalities are identical to those for the primary predicate device, as there are no differences between their features and design, including the TMS coils used. The tracking accuracy test results for the subject device are very similar to those for the secondary predicate device as they both use the exact same third party commercially available optical tracking system (Polaris).

The subject device does not introduce any new safety considerations in comparison to the primary or secondary predicate devices.

Based on the information and supporting documentation provided in the premarket notification, the QuickVision Ultimate rTMS is substantially equivalent to the cited primary and secondary predicate devices. Testing demonstrates that the QuickVision Ultimate rTMS fulfills prospectively defined design and performance specifications.