June 3, 2026

Wave Neuroscience
Leslie Prichep, PhD
Chief Scientist
1601 Dove St.
Suite 205
Newport Beach, California 92660

Re: K260402
Trade/Device Name: MeRT 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: SIG
Dated: February 5, 2026
Received: February 6, 2026

Dear Dr. Prichep:

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,

ROBERT KANG -S

for 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

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.	K260402

Please provide the device trade name(s).

MeRT System

Please provide your Indications for Use below.

The MeRT System is intended to be used as an adjunct for the treatment of adult patients suffering from Post Traumatic Stress Disorder (PTSD).

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)

WAVE NEURO

510(k) Summary

This summary of 510(k) safety and effectiveness is submitted in accordance with the requirements of 21 CFR §807.92.

Sponsor:	Wave Neuroscience 1601 Dove St STE 205 Newport Beach, CA 92660
Contact:	Leslie S. Prichep, PhD, Chief Scientific Officer
Date Prepared:	**June 2, 2026**
Trade Name:	MeRT System
Common Name:	Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions
Classification:	II
Regulation:	21 CFR 882.5802
Product Code:	SIG
Predicate Device:	K251119 MagVenture TMS Therapy System

Description of Device:
The MeRT (Magnetic EEG/ECG Resonance Therapy) System has two components: the MRT-005 machine learning -derived algorithm designed to analyze resting-state eyes-closed electroencephalogram/electrocardiogram (EEG/ECG) data to derive personalized stimulation frequency parameters for use with the second component, Transcranial Magnetic Stimulation (TMS) devices.

The system derives a recommended individualized pulse rate within the range of 8-13 Hz. This personalized frequency parameter is then used to individualize the TMS treatment settings for neuromodulation.

MRT-005 software does not generate or apply magnetic stimulation but provides computed treatment parameters to a compatible legally marketed TMS device for delivery of treatment.

Intended Use: The MeRT System is intended to be used as a TMS system for neurological and psychiatric disorders and conditions.

Indications for Use: The MeRT System is intended to be used as an adjunct for the treatment of adult patients suffering from Post Traumatic Stress Disorder (PTSD).

Comparison to Predicate Device:
The MeRT System has the same intended use and technological characteristics, and falls within the same 21 CFR § 882.5802 regulation as the predicate device, MagVenture TMS Therapy System for OCD (K251119). Both the predicate and subject devices have the same technological characteristics related to the associated TMS stimulator, electromagnetic coil, articulated arm (for positioning of the treatment coil) and proprietary software. Further, the operational aspects associated with patient treatment, including system setup, patient preparation, motor threshold determinations, coil positioning and predefined treatment stimulation parameters are essentially the same. In regard to the MeRT System's indications for use, post-traumatic stress disorder ("PTSD") is a neurological and psychiatric disorder or condition, as is obsessive compulsive disorder ("OCD") associated with the predicate device's indications for use. There is extensive evidence of similar underlying neurophysiological mechanisms of action in the two disorders, suggesting the potential for similar response to neuromodulation. The differences in design and indications for use when comparing the MeRT System and the cited predicate are not significant and do not result in differing questions of safety and effectiveness. As can be seen in the table below, the identical performance specifications can be found in the TMS Stimulator, coils for motor threshold determination and treatment coil, power source, pulse type, pulse width, cooling, max coil temperature, peak magnetic field strength, peak magnetic field gradient. Differences in performance specifications arise in the treatment protocol pulse rate per session, as the subject device personalizes the treatment protocol introducing individualized selection which results in delivery of a range of pulses per session dependent on the derived personalized treatment pulse rate. All special controls associated with 21 CFR § 882.5802 have been fulfilled and the safety and effectiveness of the MeRT System is supported by outcomes of the Randomized Controlled Trial.

A comparison of the subject and predicate devices is presented in the following table.

Table 1. Comparison of Subject and Predicate Devices

Element of Comparison	**Subject Device: MeRT System** K260402	**MagVenture TMS Therapy System for OCD K251119**	**Comparison to Predicate**
ELEMENTS OF INTENDED USE			
Intended Use	Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions	Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions.	Same

Indications for Use	The MeRT System is intended to be used as an adjunct for the treatment of adult patients suffering from Post Traumatic Stress Disorder (PTSD).	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).	Similar, PTSD and OCD are both neurological or psychiatric disorders or conditions. Each indication is supported by clinical evidence of neuromodulation and there are no new questions of safety or effectiveness. Clinical evidence of effectiveness, combined with verification and validation data fulfill the special controls and support substantial equivalence.
Prescription or OTC	Prescription (Rx) use only	Prescription (Rx) use only	Same
Use Environment	Healthcare (Clinical) environment	Healthcare (Clinical) environment	Same
TMS Delivery	Delivered by MagVenture TMS device, controlled by system software configured per MRT-005 algorithm derived treatment protocol, operating within the MagVenture range of parameters.	Delivered by MagVenture TMS device, controlled by system software within range of predefined treatment parameters.	Same, both systems are controlled by system software to deliver TMS treatment. The subject device introduces an algorithm to derive recommended treatment protocols used to configure the TMS device to deliver treatment within the equipment's inherent range of treatment parameters.
Target Population	Adult	Adult	Same
Treatment Schedule	Weeks 1-5: 1 Treatment session per day for 5 days Total 20-25 treatment sessions	Weeks 1-5: 1 Treatment session per day for 5 days Total 25 treatment sessions Week 6: 1 treatment session per day for 4 days	Same. Identical for weeks 1-4, for a total of 20-25 sessions. The predicate uses an additional week of 4-8 sessions.

		Total 4-8 additional sessions	
Area of the brain to be stimulated	Dorsomedial prefrontal cortex	Left Dorsomedial prefrontal cortex	Same. MeRT is midline stimulation of the same regions as the predicate device.
TECHNOLOGICAL CHARACTERISTICS			
Main System Components	• MeRT software (web application, driver) • TMS Stimulator with system software and GUI • Coil for motor threshold determination • Treatment coil	• TMS Stimulator with system software and GUI • Coil for motor threshold determination • Treatment coil	Same. MeRT System adds the MeRT software components. The MeRT System's compatible TMS Stimulator, coils for motor threshold determination and treatment coil are identical to the predicate device.
Treatment Protocol Pulse Rate	Personalized TMS pulse rate (8–13 Hz) via derivation from EEG analysis	Fixed 10 Hz protocol or Fixed theta burst (3 pulses at 50Hz)	Similar – The subject device personalizes the treatment protocol within a range, while the predicate device delivers a fixed treatment frequency. Pulse rate range of the MeRT System is within range of the predicate TMS capabilities (0.1-30 for MagPro R30 and 0.1-100 for MagPro X100 Hz); MeRT System introduces individualized selection to enhance clinical targeting.
Magnetic field intensity	80% of MT	100% of MT	Similar. The magnetic field intensity of the subject device is below that of the predicate.
Repetition Rate	8-13 Hz	10 Hz	Similar
Train duration	6 sec	4 sec	Similar
Inter-train interval	54 sec	26 sec	Similar
No. Of trains	30	75	Similar
Pulses per session	1440-2340	3000	Similar. MeRT System has a range of pulses per session dependent on the

			personalized treatment frequency.
Session duration	30 min	36.5 min	Similar
Coil Type	Figure-of-eight design with dual windings and an air core.	Figure-of-eight design with dual windings and an air core.	Same
Windings	2x75mm	Depending on coil variant: 2x75mm 2x97mm 2x95mm	Same
Pulse type	Biphasic	Biphasic	Same
Pulse width	290µs (±5%)	290µs (±5%)	Same
Cooling	Forced liquid cooling	Forced liquid cooling	Same
Max coil temperature	43°C	43°C	Same
Power Source	Power supply Mobile console: 110Vac, 20A	Power supply Mobile console: 110Vac, 20A	Same
Frequency range at 100%	8-13Hz	R30: 0.1-30 Hz X100: 0.1-100 Hz	Same. The MRT-005 algorithm recommended treatment protocol pulse frequency is within the range of the predicate device.
Range of % MT	80%	0-140%	Same. The MeRT System range of %MT is within the range of the predicate device.
Pulse train duration range (sec)	6	1-33	Similar, well within the range of stimulation of the predicate device.
Available stimulation in terms of SMT	Range from 0-2.2 SMT depending on coil capabilities	Range from 0-2.2 SMT depending on coil capabilities	Same
Peak magnetic field strength (T) at a depth of 2 cm	Range from 0.46-0.55T depending on coil capabilities	Range from 0.46-0.55T depending on coil capabilities	Same

Peak magnetic field gradient dB/dt (kT/s) at a depth of 2cm	Range from 9-12 kT/s depending on coil capabilities	Range from 9-12 kT/s depending on coil capabilities	Same
EEG Integration + TMS Protocol	EEG data integrated for personalized frequency	Fixed EEG frequency data, not personalized	Similar. Personalized EEG/ECG data represents additional information upon which treatment is based. Personalized EEG/ECG-driven protocol introduces no new risks; validated through software verification and clinical rationale and demonstrated in clinical study.
Output	Delivers TMS stimulation.	Delivers TMS stimulation	Same, both systems deliver TMS stimulation.
Cloud Hosting Environment	AWS Cloud	On-device hardware	Different – MeRT is cloud-based with secure, validated infrastructure; predicate is hardware-integrated.
Cybersecurity	Encrypted data, HIPAA-compliant cloud services	Not applicable	MeRT addresses cybersecurity via best practices; not relevant to predicate device design.
Algorithm	Proprietary IAF detection and frequency selection derived from EEG	Not applicable	Adds decision-support capability; validated and tested for safe implementation and clinically tested for safety and effectiveness.
Interoperability	Interfaces with compatible legally marketed TMS devices	Self-contained TMS system	MeRT requires interoperability between the MeRT software components to the compatible TMS system; predicate device contains integrated components. Interoperability is demonstrated through verification and validation.
Clinical Target	PTSD symptom reduction (e.g., PCL-5 improvement)	OCD symptom reduction (e.g., Y-BOCS)	Same – PTSD and OCD are neurological and psychiatric disorders and conditions, with the same underlying pathophysiology. Both devices target patients in

			this population to decrease symptoms.
TMS Patient Contacting Components	Coil in contact with scalp	Coil in contact with scalp	Same
EEG Patient Contacting Components	EEG headset and electrodes	Not applicable	The MRT-005 algorithm assesses an EEG file, acquired using a legally marketed EEG device, to generate recommended personalized TMS treatment protocol.
Software Validation	IEC 62304 compliant, fully validated	IEC 62304 compliant, fully validated	Same – MeRT System and the TMS device both follow standard software lifecycle and risk management processes.
Safety & Performance Data	Clinical performance, interoperability, algorithm validation	Electromagnetic and clinical testing	Same – Both demonstrate safety and effectiveness within non-clinical and clinical workflows.

Nonclinical Testing Summary:

The following performance data are provided in support of the substantial equivalence determination between the subject device, MeRT System, to the predicate device, K251119 MagVenture TMS Therapy System.

- Software verification and validation
- Integration testing demonstrates interoperability between MeRT software and compatible TMS devices
- Electrical Safety and Electromagnetic Compatibility Evaluation
- Usability Evaluation

Clinical Testing Summary:

A Prospective, Double Blind, Randomized Sham-Controlled, Clinical Trial to Evaluate the Safety and Effectiveness of Biometrics-Guided Magnetic EEG-Resonance Therapy (MeRT) Treatment of Post-Traumatic Stress Disorder

The escalating prevalence of Post-Traumatic Stress Disorder (PTSD) in both military and civilian populations has become a critical public health issue. Currently, the standard of care for treatment of PTSD includes pharmacological and psychotherapeutic interventions; however, these demonstrate only modest effectiveness and are frequently associated with treatment-limiting adverse effects. At present, there is no FDA-cleared medical device for PTSD that has the rigor of

a double-blind, randomized, sham-controlled trial to treat this debilitating condition. There is an urgent need for innovative, effective, non-pharmacologic treatment options for PTSD patients that offer favorable safety profiles compared with pharmacologic approaches to address this underserved patient population. In November 2024, Wave Neuroscience received FDA Breakthrough Device Designation, recognizing the potential for treatment with the MeRT (Magnetic EEG/ECG Resonance Therapy) System to address this unmet need.

The MRT-005 algorithm derives the individual's alpha pulse rate using EEG/ECG data with the goal of enhancing clinical targeting. This approach individualizes TMS parameters based on endogenous oscillatory characteristics as identified by the MRT-005 algorithm. By aligning stimulation frequency with each individual's alpha pulse rate using the MRT-005 algorithm, the system is designed to engage frequency-dependent neuromodulatory mechanisms and support normalization of brain function patterns and decrease symptom severity associated with PTSD. The pivotal trial was designed to evaluate the safety and effectiveness of the MeRT System as a whole, and was not structured to isolate the independent contribution of EEG-guided frequency selection relative to TMS delivered at a fixed frequency. As such, the relative contribution of the individualized frequency parameter to the observed treatment outcomes was not part of the study design.

The safety and effectiveness of treatment with the MeRT System was evaluated in a recently completed multi-site double-blind, randomized, sham-controlled pivotal trial, the results of which were presented in support of FDA clearance. The trial included adults (≥18 years) with a diagnosis of PTSD using the CAPS-5 and with a symptom severity score ≥30 on the PCL-5. The Intention to Treat (ITT) population included 158 participants, 77 of whom were assigned to the active treatment group and 81 to the sham treatment group. The study protocol included 20-25 treatment sessions (active or sham). Overall, 84% of the participants completed treatment.

The analysis of results demonstrated that active treatment with MeRT led to a statistically significant improvement in PTSD symptom severity compared with sham treatment. Treatment effects were consistent across both self-administered and clinician-administered PTSD outcome measures: the PTSD Checklist for DSM-5 (PCL-5; $p < 0.046$) and the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5; $p < 0.0006$). The PCL-5, a self-administered scale, was the study's primary outcome measure largely due to its ease of use across multiple time points. The CAPS-5 was used both to confirm PTSD diagnosis for study inclusion and as a prespecified secondary outcome measure of the change in PTSD symptom severity. Analysis of CAPS-5 results was performed after the primary PCL-5 endpoint showed statistical significance. In this study, the CAPS-5 showed an even stronger ability than the PCL-5 to demonstrate the significance of the treatment effect of the MeRT System.

The absolute magnitude of the active group pre-post treatment improvement (27 points) for the PCL-5 main outcome substantially exceeded the Department of Veterans Affairs, National Center for PTSD estimate of the minimal clinically important difference (MCID) of 8.5 to 12.5 points. The observed statistically significant differences between the active and sham groups represented a treatment effect size of approximately -0.32 in the PCL-5 and –0.51 in the CAPS-5 severity score. These are squarely within the upper range of the estimated treatment effect sizes for the two FDA-approved pharmacologic interventions for PTSD, which range from approximately -0.30 to -0.56.

Interpretation of clinical meaningfulness was informed by the FDA Patient Reported Outcomes guidance which states that clinically meaningful change thresholds are anchored at the individual level, defined as the smallest within-person change patients perceive as beneficial, and that are not intended as required between group differences. Consistent with this, the National Center for PTSD suggested PCL-5 point change threshold applies to within-person improvement in actively treated individuals, not between-group difference. In this trial, the magnitude of within-group improvement in the active treatment arm substantially exceeded established individual-level thresholds for clinically meaningful change.

Exploratory EEG analyses suggest a relationship between changes in posterior coherence and change in symptom severity in the active but not in the sham group, supporting changes in brain function in the active treatment group only. Post-hoc analyses demonstrated that the significant decrease in the PCL-5 score observed immediately post-treatment continued to improve during the follow-up period extending 2-4 months, supporting persistence of the effectiveness demonstrated in the active group. Additional post-hoc analyses defined remission using post-treatment CAPS-5 scores based on established criteria (as in K180173). Using this criteria, a significant difference was found between the active and sham groups ($p < 0.008$), with greater remission in the active group. At F2, 68.2% of participants in the active group met criteria for remission.

At the agency's suggestion, a post-hoc analysis of the relationship between outcome and pulse rate/session was conducted, dividing the full range of pulse rates derived for the active population into thirds (Low, Medium and High pulses/session groups). No significant differences were found between groups stratified by pulses/session for the PCL-5 or the CAPS; however, the Low pulse group (n=7) was underpowered, which limits conclusions in this subgroup. Importantly, the absence of a statistically significant treatment effect in this stratum should not be interpreted as evidence of equivalence between the individualized frequency (8-13 Hz) to a fixed frequency, as non-significance in an underpowered subgroup cannot be equated with established equivalence. The results of this post-hoc data analysis do not alter the overall safety and effectiveness conclusions from the Clinical Trial which was supported by the statistically significant results observed in the ITT population.

Post-hoc stratified analyses also revealed that the comparison of CAPS-5 outcomes between the High and Medium pulse frequency strata approached statistical significance (p=0.067). While this difference did not reach the conventional threshold for significance, it is reported here in the interest of a complete and transparent account of the stratified analyses. This finding does not alter the overall safety and effectiveness conclusions, which remain supported by the statistically significant results observed in the ITT population.

With respect to safety, there were no statistically significant differences between the active and sham treatment groups, with a similar number of participants reported Treatment-Emergent Adverse Events (TEAEs); and a similar total number of TEAEs reported in both treatment groups. There was no serious adverse event in this study. Based on zero serious adverse events in the active treatment group, the upper bound of the 95% confidence interval for the serious adverse event rate is estimated to be less than 4%.

The results of this trial support that treatment with the MeRT System is associated with statistically significant and clinically meaningful reductions in PTSD symptom severity, with a very favorable safety profile. These results highlight the potential of the MeRT System to add an innovative, safe, effective, non-pharmacological treatment option for the PTSD population.

Conclusions:

The MeRT System and predicate device, MagVenture TMS Therapy System (K251119) are substantially equivalent with respect to intended use, safety and performance. All applicable special controls associated with 21 CFR § 882.5802 have been fulfilled and the safety and effectiveness of the MeRT System is supported by outcomes of the Randomized Controlled Trial. In accordance with 21 CFR § 807.100(b), the subject device and the predicate, cleared by FDA and legally marketed in the United States, are substantially equivalent.