February 13, 2025

Neuromodulatory Devices & Applications
% Tyler Ting
Director of Regulatory Affairs
Avio Medtech Consulting
2300 Myrtle Ave Suite 200
St. Paul, Minnesota 55114

Re: K243319
Trade/Device Name: Ampa One System (AMPA-001)
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: January 14, 2025
Received: January 14, 2025

Dear Tyler Ting:

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243319

Device Name

Ampa One System (AMPA-001)

Indications for Use *(Describe)*

The Ampa One System is intended for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K243319

In accordance with 21 CFR 807.92 the following summary information is provided:

Contact Details
21 CFR 807.92(a)(1)

Applicant Name:	Neuromodulatory Devices & Applications
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Device Trade Name
21 CFR 807.92(a)(2)

Device Trade Name:	Ampa One System (AMPA-001)
Common Name:	Repetitive transcranial magnetic stimulation system
Classification Name:	Transcranial Magnetic Stimulator
Regulation Number	882.5805
Product Code(s)	OBP

Legally Marketed Predicate Devices
21 CFR 807.92(a)(3)

510(k)	Trade Name	Product Code
K173620	MagVita TMS Therapy System w/Theta Burst Stimulation	OBP
K220819	Brainsway Deep TMS System	OBP

Device Description Summary
21 CFR 807.92(a)(4)

The Ampa One System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic fields to induce electrical currents in brain tissues to target specific regions of the cerebral cortex. The system contains two different coils for targeting different regions of the brain. The L Coil is designed to target the left dorsolateral prefrontal cortex (DLPFC). The M Coil is designed to target the bilateral prefrontal cortex (DMPFC). Both coils are used within the Ampa One System to treat Major Depressive Disorder (MDD) in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Transcranial magnetic stimulation (TMS) is a non-invasive technique for stimulating brain and neural tissue. The principle of magnetic stimulation is implicit in Faraday's law. The pulses of current are generated with a circuit containing a capacitor connected to the stimulating coil. With the capacitor charged to a certain level, the conducting state will cause the discharging of the capacitor through the coil. A magnetic field is generated proportional to this current. The rapid change in the magnetic field induces a current in conducting materials e.g. the body tissue. If the current induced in the human body is of sufficient amplitude and duration, it will excite neurons.

The Ampa One System is an integrated system composed of the following hardware and software components with associated functions to enable its intended use:

- Ampa L and M Coils - MT determination and Depression treatment
- Bridge Box & cables - Allows connection to the pulse generator and control treatment protocols from the pulse generator and Ampa tablet with software
- Ampa tablet with software - The software interface for operators to control TMS treatment
- Ampa Magic Arm - Support system to securely hold the coils in place during treatment
- Neuronavigation Cap - Fabric cap worn by patient with integrated markings for determination of cerebral cortex treatment targets

The system is intended to be used with the MagVenture MagPro R30 Pulse Generator (K230014) and cannot be used without a compatible pulse generator.

The system comes with a tablet preloaded with a mobile app containing the software interface for operation of the system.

Intended Use/Indications for Use
21 CFR 807.92(a)(5)

The Ampa One System is intended for 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 Ampa One System and the predicate devices have the same indications for use.

Technological Comparison
21 CFR 807.92(a)(6)

The AMPA One System has similar technological characteristics to the predicate devices and the minor ancillary differences between the two devices do not raise different questions regarding safety and effectiveness.

The new device and predicate devices share the same technological characteristics to achieve their intended use of treating MDD using repetitive magnetic fields to induce electrical firing in the cerebral cortex. The Ampa One System coils and the predicate devices' coils are both wound coils of the same design where pulses of electric current are passed to deliver non-invasive, magnetic fields which induce electrical currents in targeted regions of the cerebral cortex.

The design of the M and L coils were based on the selected predicate devices, the MagVita B70 (K173620) and the BrainsWay H7 (K220819). The process of designing the coil windings used state-of-the-art simulations in collaboration with a renowned expert in TMS coil analysis.

Because of the design process, the magnetic fields produced by the Ampa One System coils and the predicates are nearly indistinguishable from each other. The correlation coefficient between the L coil and the B70 coil is 0.981 and the correlation coefficient between the M coil and the H7 is 0.986. The concomitant induced electrical field distributions are also equally identical, with correlation coefficients of 0.985 and 0.997 for the L and M coil, respectively.

The minor differences between the subject device and the predicate devices are: 1. the cooling systems of the coils; 2. the software used to control the treatment; and 3. the use of an integrated camera and premarked patient cap for patient positioning.

The Ampa One System uses a phase change material alongside a software controlled cutoff to maintain both operational temperatures and prevent thermal harm whereas the predicate devices use active cooling systems. The Ampa One System has its own software within a preloaded tablet to control treatment parameters whereas the predicate devices' software comes on their own capital equipment. The Ampa One System uses an integrated camera in the coil and software to control coil positioning whereas the predicate devices' use operator determined markings on the patient cap (K173620) and head positioning straps (K220819) to achieve accurate and reliable coil positioning. These represent the differences in technological characteristics.

Substantial Equivalence Table

	Subject Device: **Ampa One System**	**Predicate for Ampa One System, L Coil** **MagVita TMS Therapy System w/Theta Burst Stimulation** **K173620**	**Predicate for Ampa One System, M Coil** **Brainsway Deep TMS System** **K220819**
Product Code, Device Risk Classification	OBP Class II	OBP Class II	OBP Class II
Indications for Use	The Ampa One System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode.	The MagVita TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode.	The BrainsWay Deep TMS™ is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode.
Target Population	Adult subjects with Major Depressive Disorder	Adult subjects with Major Depressive Disorder	Adult subjects with Major Depressive Disorder with comorbid anxiety symptoms
Energy Used / Delivered	Electromagnetic Energy is delivered	Electromagnetic Energy is delivered	Electromagnetic Energy is delivered
Area of brain to stimulated	Ampa L-Coil: Head – theta burst stimulation to the left dorsolateral prefrontal cortex (DLPFC) Ampa M-Coil: Head – stimulation to the dorsomedial prefrontal cortex	Theta burst stimulation to the left DLPFC	Stimulation to the DMPFC

	Subject Device: **Ampa One System**	**Predicate for Ampa One System, L Coil** **MagVita TMS Therapy System w/Theta Burst Stimulation** **K173620**	**Predicate for Ampa One System, M Coil** **Brainsway Deep TMS System** **K220819**
	(DMPFC)		
Applicator: Configuration Core Material	<u>Ampa L-Coil:</u> Figure-of-eight coil Air core <u>Ampa M-Coil:</u> Figure-of-eight coil Air Core	Figure-of-eight coil Air core	Figure-of-eight coil Air core
Performance of Treatment Protocol		**Intermittent Theta Burst Stimulation (iTBS) Treatment**	**Brainsway H7 Coil for treatment of MDD and Depression with Comorbid Anxiety**
Physical unit of amplitude setting (e.g., coil current, peak magnetic field) at coil and its relation to the SMT unit	<u>L Coil</u> 0 – 2.03 SMT (Standard Motor Threshold) <u>M Coil</u> 0 – 1.76 SMT	0 – 1.7 SMT	0 – 1.4 SMT
Patient Contacting Materials	Treatment Cap	Treatment Cap	Treatment Cap
Coil Positioning System	Cap positioned in relation to nasion	Cap positioned in relation to nasion	Cap positioned in relation to nasion
Sterility	Not Applicable	Not Applicable	Not Applicable
Electrical safety	Complies with IEC 60601-1 and IEC 60601-1-2	Complies with IEC 60601-1 and IEC 60601-1-2	Complies with IEC 60601-1 and IEC 60601-1-2
Treatment stimulation parameters	<u>L Coil</u> Waveforms: 275 μs biphasic	Waveforms: 290 μs biphasic	

	Subject Device: **Ampa One System**	**Predicate for Ampa One System, L Coil** **MagVita TMS Therapy System w/Theta Burst Stimulation** **K173620**	**Predicate for Ampa One System, M Coil** **Brainsway Deep TMS System** **K220819**
	sinusoid Magnetic field strength: 120% MT (motor threshold) Repetition rate: 50 Hz Train duration: 2 sec* Inter-train interval: 8 secs Burst pulses: 3 Bursts: 200 Inter-pulse interval: 20 msec Number of trains: 20 Numbers of pulses/session: 600 Total duration: 3 min 9 sec <u>M Coil</u> Waveform: 370 µs biphasic sinusoid Magnetic Field Strength: 120% MT Repetition rate: 18 Hz Train duration: 2 sec* Inter-train interval: 20 sec Number of trains: 55 Magnetic Pulses per Session: 1980 Treatment Session Duration: ~ 20 min	sinusoid Magnetic field strength: 120% MT Repetition rate: 50 Hz Train duration: 2 sec Inter-train interval: 8 secs Burst pulses: 3 Bursts: 200 Inter-pulse interval: 20 msec Number of trains: 20 Numbers of pulses/session: 600 Total duration: 3 min 9 sec	Waveform: 370 µs biphasic sinusoid Magnetic Field Strength: 120% MT Repetition rate: 18 Hz Train duration: 2 sec Inter-train interval: 20 sec Number of trains: 55 Magnetic Pulses per Session: 1980 Treatment Session Duration: ~ 20 min

* Maximum Safe Train Duration (seconds) Limits for Avoiding Seizure limits from Table 2 of the FDA Special Controls Guidance[1] are equivalent to the predicate devices, and therefore safe as prior clinical testing has established a minimal risk of seizure for these durations.

[1] https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/repetitive-transcranial-magnetic-stimulation-rtms-systems-class-ii-special-controls-guidance

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

Nonclinical testing evaluated the Ampa One System's performance to be equivalent in terms of safety and effectiveness compared to the predicate devices. The suite of testing to demonstrate substantial equivalence can be divided into two aspects: safety (function and compatibility) and effectiveness (magnetic characteristics).

Safety testing established that the Ampa One System is able to function in its configuration with the MagVenture R-30 pulse generator to perform its intended use. Safety is defined as functioning with risks assessed of TMS therapy mitigated through design.

Effectiveness testing established that the Ampa One System produced equivalent magnetic characteristics compared to the predicate devices. Specifically, testing demonstrated that the amplitude of the magnetic field strength as a function of power input, and the spatial characteristics of the magnetic field produced were identical between the Ampa One coils vs. their respective predicate device coils.

Development and testing of the Ampa One System was performed in conformance with the FDA Special Controls Guidance on Transcranial Magnetic Stimulator devices. Bench testing was performed in alignment with this Guidance document in order to support substantial equivalence.

Standards Conformance
The Ampa One System Complied with the following voluntary consensus standards:

Risk
- ISO 14971 Third Edition 2019-1 | Medical devices – Application of risk management to medical devices

Electrical Safety
- IEC 60601-1 Edition 3.2 2020-08 Consolidated Version | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Electromagnetic Compatibility (EMC)
- IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

Software Development
- IEC 62304 Edition 1.1 2015-06 Consolidated Version | Medical device software – Software life cycle processes

Biocompatibility
- ISO 10993-1 Fifth edition 2018-08 | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Shipping and Transportation
- ASTM D4169-22 | Standard Practice for Performance Testing of Shipping Containers and Systems

- ASTM D4332-22 | Standard Practice for Conditioning Containers Packages or Packaging Components for Testing

Conclusion

The evaluation of the subject device's safety and effectiveness has been performed as per the information that is listed above. Based upon this information, the subject device is substantially equivalent to the predicate devices.