June 26, 2025

Neuromodulatory Devices & Applications
℅ Matthieu Kirkland
Head of Regulatory Affairs
Avio Medtech Consulting
2300 Myrtle Ave, Suite 200
St. Paul, Minnesota 55114

Re: K251210
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: May 29, 2025
Received: May 29, 2025

Dear Matthieu Kirkland:

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,

PAMELA D. SCOTT -S

Digitally signed by PAMELA D. SCOTT -S
Date: 2025.06.26 23:32:03 -04'00'

Pamela D. Scott
Assistant Director
DHT5B: Division of Neuromodulation and
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OHT5: Office of Neurological and
Physical Medicine Devices
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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)*

K251210

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) #:

510(k) Summary

Prepared on: 2025-06-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Neuromodulatory Devices & Applications
Applicant Address	501 W. Broadway Suite 1025 San Diego CA 92101 United States
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Correspondent Contact	Mr. Matthieu Kirkland
Correspondent Contact Email	Matthieu@aviomedtech.com

Device 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)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K243319	Ampa One System	OBP

Device Description Summary

21 CFR 807.92(a)(4)

Please note the subject device is nearly identical to the device cleared in K243319. The only change to the System is that the Bridge Box for connection to the MagVenture MagPro R30 pulse generator and the MagVenture MagPro R30 pulse generator itself have been replaced with an Ampa Pulse Generator. The Ampa One System with the Ampa Pulse Generator is substantially equivalent to its previously cleared design.

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
• Ampa Pulse Generator - Provide Electrical power to the coils
• Ampa Control Pad - The software interface for operators to control TMS treatment
• Axon Cable - Provides connections between the Ampa Pulse Generator and Ampa Control Pad
• 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 comes preloaded with a mobile app on the Ampa Control Pad 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 device have the same indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has nearly identical technological characteristics to the predicate device.

Both devices have identical treatment protocol parameters (e.g., repetition rate, pulses per train, number of trains, number of pulses, inter train interval, treatment time) and consist of the same general TMS system components (e.g., coils, pulse generator or pulse generator connector, navigation cap, tablet with software, coil holder arm). The only difference is that rather than using a bridging connector (i.e., Bridge Box) to connect to an external pulse generator (i.e., MagVenture MagPro R30), the subject device includes an Ampa Pulse Generator and does not require a bridging connector.

The Ampa Pulse Generator produces pulsed electrical current, which generates a time-varying magnetic field through the coil. It was intentionally designed & developed to closely match the well-known MagVenture R30, utilizing a nearly identical electrical topology to achieve functionally equivalent output.

All coils are unmodified within the subject device and identical to those in the predicate device clearance. Additional performance testing has been conducted using the well-established methods in the rTMS Special Controls guidance to evaluate the change and ensure both devices provide the same reasonable expectation of safety and effectiveness (e.g., methods, protocols, and acceptance criteria used to support clearance of K243319).

Please note that there is an attached Substantial Equivalence Table after the conclusions section with a complete comparison and analysis of device parameters.

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 device. 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 Ampa One 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 substantially 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 substantially equivalent between the subject and predicate device.

Development and testing of the Ampa One System was performed in conformance with the FDA Special Controls Guidance on Transcranial Magnetic Stimulator devices.

Clinical Data was not applicable for this submission.

Testing in accordance with the FDA Special Controls Guidance and voluntary consensus standards demonstrate that the Ampa One System achieves substantially equivalent safety and effectiveness compared to the legally marketed predicate devices.

	Modified Device: **Ampa One System**	**Predicate Device:** **Ampa One System (K243319)**	**Comments**
Product Code, **Device Risk** **Classification**	OBP Class II	OBP Class II	Identical
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 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.	Identical
Target Population	Adult subjects with Major Depressive Disorder	Adult subjects with Major Depressive Disorder	Identical
Energy Used / Delivered	Electromagnetic Energy is delivered	Electromagnetic Energy is delivered	Identical
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 dorsolateral prefrontal cortex (DLPFC)	Ampa L-Coil: Head – theta burst stimulation to the left dorsolateral prefrontal cortex (DLPFC) Ampa M-Coil: Head – stimulation to the dorsolateral prefrontal cortex (DLPFC)	Substantially Equivalent
Components	Ampa L and M Coils	Ampa L and M Coils	Identical
	Ampa Pulse Generator	Bridge Box	Substantially Equivalent. The Bridge Box, which allowed connection to the MagVenture MagPro R30 Pulse Generator, has been replaced with an Ampa Pulse Generator.
	Neuronavigation Cap	Neuronavigation Cap	Identical
	Ampa Control Pad	Ampa Tablet	Identical – Name Change
	Ampa Magic Arm	Ampa Magic Arm	Identical
Applicator: **Configuration** **Core Material**	Ampa L-Coil: Figure-of-eight coil Air core Ampa M-Coil: Figure-of-eight coil Air Core	Ampa L-Coil: Figure-of-eight coil Air core Ampa M-Coil: Figure-of-eight coil Air Core	Identical

	Modified Device: **Ampa One System**	**Predicate Device:** **Ampa One System (K243319)**	**Comments**
Performance of Treatment Protocol			
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 – 1.7 SMT <u>M Coil</u> 0 – 1.4 SMT	<u>L Coil</u> 0 – 2.0 SMT <u>M Coil</u> 0 – 1.7 SMT	Substantially Equivalent
Patient Contacting Materials	Treatment Cap	Treatment Cap	Identical
Coil Positioning System	Cap positioned in relation to nasion	Cap positioned in relation to nasion	Identical
Electrical safety	Complies with IEC 60601-1 and IEC 60601-1-2	Complies with IEC 60601-1 and IEC 60601-1-2	Identical
Treatment stimulation parameters	<u>L Coil</u> Waveforms: 210 µs biphasic sinusoid Magnetic field strength: 120% of patients' hand-twitch motor threshold (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 <u>M Coil</u> Waveform: 210 µs biphasic sinusoid Magnetic Field Strength: 120% of patients' hand-twitch motor threshold (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	<u>L Coil</u> Waveforms: 290 µs biphasic sinusoid Magnetic field strength: 120% of patients' hand-twitch motor threshold (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 <u>M Coil</u> Waveform: 290 µs biphasic sinusoid Magnetic Field Strength: 120% of patients' hand-twitch motor threshold (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	Substantially Equivalent Substantially Equivalent