July 3, 2025

The Magstim Company Limited
Daniel Gregory
Principal Systems Engineer
Spring Gardens, Whitland
Carmarthenshire, SA34 0HR
United Kingdom

Re: K250286
Trade/Device Name: Rapid^2 Magnetic Stimulators (Magstim Rapid^2, Magstim Super Rapid^2, Magstim Super Rapid^2 Plus^1)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: QPL
Dated: June 11, 2025
Received: June 11, 2025

Dear Daniel Gregory:

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,

Amber T. Ballard -S

Amber Ballard, PhD
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DHT5B: Division of Neuromodulation and
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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.

510(k) Number *(if known)*
K250286

Device Name
Rapid2 Magnetic Stimulators (Magstim Rapid2, Magstim Super Rapid2, Magstim Super Rapid2 Plus1)

Indications for Use *(Describe)*
Rapid2 Magnetic Stimulators (Magstim Rapid2, Magstim Super Rapid2, Magstim Super Rapid2 Plus1) are intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years or older.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K250286

Manufacturer and 510(k) Owner

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Date Prepared: July 3, 2025

Device Information

Proprietary Name/Trade Name:	Rapid^2 Magnetic Stimulators **(** Magstim Rapid^2, Magstim Super Rapid^2, Magstim Super Rapid^2 Plus^1)
Common Name:	Electromagnetic Stimulator, Pain Relief
Regulation Number:	21 CFR 882.5890
Regulation Name:	Transcutaneous electrical nerve stimulator for pain relief
Class:	Class II
Product Code:	QPL
Review Panel:	Physical Medicine

Predicate Device

The Rapid^2 Magnetic Stimulators (K250286) are substantially equivalent to the following predicate:

510(k) Number	Predicate Device Name / Manufacturer	Regulation / Product Code
K230014	Device Name: MagVenture Pain Therapy: MagPro R30, MagPro R30 with MagOption, MagPro X100, MagPro X100 with MagOption. Manufacturer: Tonica Elektronik A/S.	21 CFR 882.5890 QPL

Device Description

The Magstim Rapid^2, Magstim Super Rapid^2, Magstim Super Rapid^2 Plus^1 (herein collectively referred to as "Rapid^2 Magnetic Stimulators") are computerized, electromechanical medical devices that provide brief and focused magnetic pulses in order to non-invasively stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years or older. The subject device is intended to be used in hospitals and clinics such as pain management clinics.

Rapid^2 Magnetic Stimulators are integrated systems consisting of a combination of hardware, software, and accessories. Rapid^2 Magnetic Stimulators are offered in multiple configurations:

- Rapid^2
- Super Rapid^2
- Super Rapid^2 Plus^1

All three configurations have identical intended use/indications for use, common specifications, equivalent performance characteristics and equivalent composition to each other. Specifically, Rapid^2 and Super Rapid^2 have received prior clearance under K051864 for Peripheral Nerve Stimulation (Product Code: GWF, Regulation 21 CFR 882.1870). All Rapid^2 Magnetic Stimulators are made up of components that have received prior clearance under K051864 (e.g., the 3190-00, 3192-00 and 3193-00 coils) and components which have received prior clearance under K051864 but have received modifications due to aspects like obsolescence (Mainframe, Power Supply etc.).

All Rapid^2 Magnetic Stimulators are composed from the following main components:
- Stimulating Unit & Power Supply
- User Interface
- Stimulating Coil
- System and Stimulating Coil Cart and Holding Arm

Rapid^2 Magnetic Stimulators include temperature monitoring via two independent temperature sensors to ensure surfaces of the coils do not reach unacceptable levels. The cut-off is set to act at 40°C at which point the system will automatically be disabled. Over-temperature conditions are also communicated on the User Interface (UI) via a temperature gauge and alarm system. Rapid^2 Magnetic Stimulators also includes the 3910-00 air-cooled coil to further mitigate any temperature conditions. The 3910-00 air-cooled coil comes with all 3 configurations (Rapid^2, Super Rapid^2 and Super Rapid^2 Plus^1) as standard.

Indications for Use

The Rapid^2 Magnetic Stimulators are intended to stimulate peripheral nerves for relief of chronic intractable, post- traumatic and post-surgical pain for patients 18 years or older.

Comparison of Technological Characteristics

Table 1: Substantial Equivalence Summary

	Rapid^2 Magnetic Stimulators *(Subject Device)*	**MagVenture Pain Therapy** *(Predicate Device)*	**Evaluation of Differences**
Manufacturer	Magstim Company Limited	Tonica Elektronik A/S	
Device Name	Rapid^2 Magnetic Stimulators	MagVenture Pain Therapy	
Device Configurations	Rapid^2, Super Rapid^2, Super Rapid^2 Plus^1	MagPro R30, MagPro R30 with MagOption, MagPro X100, MagPro X100 with MagOption	
510(k) number(s)	K250286	K230014	
Device regulation and product code	21 CFR 882.5890 QPL	21 CFR 882.5890 QPL	Identical
Indications for Use	Rapid^2 Magnetic Stimulators are intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years or older.	The MagVenture Pain Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years or older.	Identical
Anatomical Sites	Any area, such as hand, arm, waist, buttock, thigh, calf, back and lower back etc.	Any area, such as hand, arm, waist, buttock, thigh, calf, back and lower back etc.	Identical
Treatment Facilities	Hospitals & Clinics	Hospitals & Clinics	Identical
Treatment Time	13 minutes per session (800 seconds)	13 minutes per session (800 seconds)	Identical

	Rapid^2 Magnetic Stimulators *(Subject Device)*	**MagVenture Pain Therapy** *(Predicate Device)*	**Evaluation of Differences**
Pulse Frequency	Rapid^2: 0.1 – 50 Hz (pps) Super Rapid^2 and Super Rapid^2 Plus^1: 0.1 – 100 Hz (pps)	MagPro R30 & MagPro R30 with MagOption: 0.1 – 30 Hz (pps) MagPro X100 & MagPro X100 with MagOption: 0.1 – 100 Hz (pps)	Similar range as the predicate device.
Pulse Amplitude	0 – 100%	0 – 100%	Identical
On-cycle duty period	2-800 Seconds (0.5 Hz and up to 400 pulses)	2-800 Seconds (0.5 Hz and up to 400 pulses)	Identical
Off-cycle rest period	N/A	N/A	Identical.
Maximum Repetition Rate	Rapid^2: 50Hz Super Rapid^2: 100Hz Super Rapid^2 Plus^1: 100Hz	MagPro R30 & MagPro R30 with MagOption: 30 pulses per second MagPro X100 & MagPro X100 with MagOption: 100 pulses per second	Upper limit identical when compared to the predicate device. *Refer to SE Note 1*
Pulse Width	Biphasic (300-425 μs)	Biphasic (280-320 μs)	Pulse width range is similar when compared to predicate. *Refer to SE Note 2*
Pulse Mode	Standard	Standard	Same pulse mode as the predicate
Maximum Output Power	Rapid^2: 100% at 15Hz/pps Super Rapid^2: 100% at 25Hz/pps Super Rapid^2 Plus^1: 100% at 41Hz/pps	100% at 15Hz/pps	Substantially equivalent maximum output to predicate device. *Refer to SE Note 1*
Waveform	Biphasic, Biphasic Burst	MagPro R30: Biphasic MagPro R30 with MagOption: Biphasic, Monophasic MagPro X100: Biphasic, Biphasic Burst, Monophasic MagPro X100 with MagOption: Biphasic, Halfsine, Biphasic Burst, Monophasic	Substantially equivalent – waveform produced by subject device is within the range available in the predicate device.

Criteria	Rapid^2 Magnetic Stimulators *(Subject Device)*	MagVenture Pain Therapy *(Predicate Device)*	Evaluation of Differences
Maximum Coil Temperature	40^{O}C	43^{O}C	both subject and predicate devices automatically disable if max. temperature is reached.
Peak Magnetic Field at Coil Surface (T)	1.0-1.5T	1.15-2.6T	Substantially equivalent – peak field produced is a subset of the predicate device. *Refer to SE Note 2*
Peak Magnetic Field Gradient dB/dt at coil center, 20mm distance from the coil surface	9-12kT/s	9-24kT/s	Substantially Equivalent – Peak Rate of Change at 20mm is subset of the predicate device. *Refer to SE Note 2*
Software or Firmware Control	Yes	Yes	Identical
Power Source	Power Supply via dedicated power supply modules each using a separate input mains line cord. Power Supply: 115/230/240V ~50/60Hz	Power Supply via Isolation Transformer Power Supply: 120V~ 50/60Hz	Similar
Power Consumption	230/240V Systems – 3000VA peak per input 115V Systems – 2300VA peak per input	Maximum 2700VA	Similar
User Interface	LCD Capacitive Touchscreen	LED Display	Similar
Housing Material Construction	Stimulator: PUR, Stainless/Galvanized Steel Coils: PC, PUR	Stimulator: Aluminum, Aluzinc Coils: PVC, ABS, PA, POM	Similar
Applied Parts	Magnetic Coils: 3190-00 Double 70mm Remote (K051864) 3192-00 90mm Remote (K051864)	Magnetic Coils: MC-140-II (K061645) MCF-140 (K061645)	Substantially equivalent coil range to predicate. *Refer to SE Note 2*

Criteria	Rapid^2 Magnetic Stimulators *(Subject Device)*	MagVenture Pain Therapy *(Predicate Device)*	Evaluation of Differences
	3193-00 90mm Standard (K051864) 3910-00 Double 70mm Air Film Coil (K080499) 4102-00 D70^2 (K130403) 4150-00 D70 Alpha Coil (New) 4170-00 D70 Alpha Coated Flat Coil (New) 4189-00 D60 Alpha Coated Branding Iron Coil (New) 4190-00 D60 Alpha Coated Flat Coil (New) 4510-00 D70 Alpha Coated Branding Iron Coil (New)	RT-120-II (K061645) MMC-90 (K061645) MCF-125 (K071821) Cool-B65 (K071821) Cool-125 (K071821)	
Applied Part Area	*Butterfly Coils (3190-00, 3910-00, 4102-00, 4150-00, 4170-00, 4189-00, 4190-00, 4510-00):* 152mm – 191mm *Circular Coils (3192-00, 3193-00):* 124.5mm	*Butterfly Coils:* 150mm *Circular Coils:* 110-126mm *Special Coils:* 160x80 mm	Substantially equivalent. *Refer to SE Note 2*
Sterilization	Non-sterile when used.	Non-sterile when used.	Identical
Electrical Safety	Complies with IEC 60601-1 Ed. 3.2	Complies with IEC 60601-1 Ed. 3.1	Same – just newer edition of the standard.
Mechanical Safety	Complies with IEC 60601-1 Ed. 3.2	Complies with IEC 60601-1 Ed. 3.1	Same – just newer edition of the standard.
Thermal Safety	Complies with IEC 60601-1 Ed. 3.2	Complies with IEC 60601-1 Ed. 3.1	Same – just newer edition of the standard.
Radiation Safety	No radiation generated.	No radiation generated.	Same.

	Rapid^2 Magnetic Stimulators *(Subject Device)*	MagVenture Pain Therapy *(Predicate Device)*	Evaluation of Differences
Biocompatibility	Complies with the following parts of the ISO 10993 series: ISO 10993-1, ISO 10993-5, ISO 10993-10	Complies with ISO 10993	Same as predicate.
Standards	Company Complies with ISO 13485 Device Complies with IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 and IEC 62366-1	Company Complies with EN ISO 13485	Same/Equivalent standards met as the predicate device.

Substantial Equivalence Note/Discussion Point 1 – Comparing Repetition Rate and Power Capabilities of the Subject and Predicate Devices:

Relevant Characteristics from SE Table – Device Configurations, Maximum Repetition Rate, Maximum Output Power

The pulse frequencies of 0.1-50Hz and 0.1-100Hz as well as the maximum repetition rates of 100Hz (pps) are similar to the predicate device. The difference from the subject device compared to the predicate device is the maximum frequency that can be delivered at maximum machine output. This does not raise any differing questions of safety or effectiveness as:

1. The subject device states that the treatment parameter is 0.5Hz within the instructions for use, as well as being the default options provided on the system user interface. The recommended pain therapy protocol is provided by default on the system and cannot be modified, overwritten or deleted by a user.
    a. Three to four treatments over two months and maintenance therapy every 6 to 8 weeks is recommended.
    b. Treatment Level: Individually estimated (% of maximum machine output).
    c. Repetition Rate: 0.5Hz/PPS
    d. Pulse per Train: 10
    e. Number of Trains: 40
    f. Number of Pulses: 400
    g. Inter-Train Interval: 2s
    h. Treatment Time: 13min
2. Both the instructions for use and User Interface provide statements where parameters are displayed that Treatment parameters (e.g., repetition rate, pulses per train, number of trains, number of pulses, inter train interval, treatment time) that are not included in the treatment protocol have not been evaluated for effectiveness in the relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.

Substantial Equivalence Note/Discussion Point 2 – Comparing Magnetic Coils between the Subject and Predicate Devices:

Relevant Characteristics from SE Table – Pulse Width, Peak Magnetic Field at Coil Surface, Peak Magnetic

Field Gradient at 20mm from Coil Center, Applied Parts/Applied Parts Area

The subject device has equivalent coils which have slightly different characteristics compared to the predicate device. These characteristics slightly alter the magnetic field spatial distribution. This does not raise any differing questions of safety or effectiveness as:

1. The subject device nominal peak magnetic field outputs of the subject device (1.0T – 1.5T) have different maximum values to that of the predicate device (1.15T – 2.6T). This does not raise any differing questions of safety and effectiveness because the subject device has a smaller peak over a longer period, compared to the predicate device which has a larger peak over a shorter period.
2. As demonstrated by the performance data within this submission, the coil E-Field decay, linearity of output as well as electric & magnetic field spatial distributions are very similar and would produce equivalent effects at 0-2cm from the coil surface.
3. The subject device has the same type of coil configurations as the predicate device, which are circular and butterfly coils.
4. The construction of the coils of the subject device matches the predicate device as described in K230014 – A copper winding element encapsulated in a plastic housing.
5. Finally, the pulses produced by the subject device are all Biphasic waveforms equivalent to the predicate device. Some pulse widths of coils of the subject device (300ms – 425ms) do exceed that of the predicate device (280ms – 320ms) but no differing questions of safety or effectiveness are raised as the higher pulse widths and lower peak magnetic field of the subject device result in an equivalent level of energy delivered into the tissue as the lower pulse widths and higher peak magnetic field of the predicate device.

Summary of Non-Clinical Testing

Non-clinical testing was performed to demonstrate the subject Rapid^2 Magnetic Stimulators raise no differing questions of safety or effectiveness when compared to the predicate device cleared under K230014.

Electrical, Mechanical & Thermal safety was performed on all device configurations (Standard Rapid^2, Super Rapid^2 and Super Rapid^2 Plus^1) and demonstrated compliance to the IEC, ANSI/AAMI, CAN/CSA and BS EN variants of 60601- 1 (Ed. 3.2). The proposed device configurations were assessed for operating under both 115V and 230V/240V (Split Phase) at 60Hz mains power supply. Additionally, in house thermal testing was performed to demonstrate that in representative conditions, the systems and their compatible coils could successfully deliver the recommended pain therapy protocol with no overheating or compromising of safety. In addition to 60601-1, the device was also assessed to the collateral standard for alarm systems and complies with 60601-1-8.

Electromagnetic Compatibility was assessed, and the subject device was found to be compliant to the requirements of IEC 60601-1-2 (Ed. 4.1) The test report and certification of conformance show that the emissions and immunity testing performed per CISPR 11, IEC 61000- 3 and IEC 61000-4, respectively, resulted in passing results. This standard provides an adequate level of electromagnetic compatibility according to the risk assessment and essential performance of the proposed device.

Software Verification and Validation was performed in accordance with 62304 to ensure the software systems do not contribute to any unacceptable risk. Software was verified using methods such as 'Open Box' testing where fault scenarios were generated and backup hardware measures were verified to ensure no unacceptable risk. A risk management process in compliance with ISO 14971:2019 was used to perform risk management activities and control risk. Risk management and software development also included

security assessment utilizing AAMI TIR57. Security risk was assessed and controlled as appropriate based on the intended use environment and the functions of the device. Further, the software was validated as part of the Human Factors and Usability Engineering process.

Device biocompatibility was assured via application of the ISO 10993 series of standards. The applied parts of the system that are regularly in contact with the operator and patient (stimulating coils) use suitable biocompatible materials. Testing has been performed on the applied part materials commensurate to the risk and use of the device including Skin Irritation, Cytotoxicity and Skin Sensitization testing.

Acoustics testing was performed as part of the 60601-1 type testing, as well as separately in-house to ensure the device does not reach any excessive or unacceptable noise levels. The results demonstrate a substantially equivalent level of acoustic output. As stated in the Labeling (Operating Manual/Instructions for Use) the patient must always wear earplugs or similar hearing protection devices with a rating of 30dB of noise reduction when being treated with Rapid^2 Magnetic Stimulators.

Finally, device output characteristics was quantitatively characterized for each of the compatible applicating coils described within this submission. The method for testing was informed by methods of evaluation used for Transcranial Magnetic Stimulators - specifically following guidance from "Repetitive Transcranial Magnetic Stimulation (rTMS) Systems – Class II Special Controls Guidance for Industry and FDA Staff" – July 26, 2011.

For each of the sample coils:

1. an electric field distribution plot was created in a volume of 20cm * 20cm * 3cm.
2. Magnetic field distribution plots were created in a volume of 20cm * 20cm * 4cm, plotting both the Magnetic Flux Density and the dB/dt (Magnetic Field Rate of Change).

This resulted in the following characteristics and values being obtained:

1. Peak Magnetic Field Strength (T) at Coil Surface
2. Peak Magnetic Field Strength (T) at 2cm from Coil Surface
3. Peak Magnetic Field Gradient (dB/dt, kT/s) at Coil Surface
4. Peak Magnetic Field Gradient (dB/dt, kT/s) at 2cm from Coil Surface
5. Output Waveform Oscilloscope Traces
6. Electric Field Spatial Distribution Plots for each Sample Coil in a 20cm * 20cm * 3cm region with 5mm resolution
7. Magnetic Flux Density and dB/dt Plots for each Sample Coil in a 20cm * 20cm * 4cm region with 2cm resolution
8. Electric Field Decay as a Function of Distance from the Coil Surface.
9. Linearity of Output

The above non-clinical testing resulted in a comprehensive collection of data that demonstrates substantially equivalence between the subject device and the predicate device for the stimulation of peripheral nerves for relief of chronic intractable, post traumatic and post-surgical pain.

Conclusion

In conclusion, the Rapid^2 Magnetic Stimulators can be deemed to be as safe and effective as the predicate

device cleared under K230014 for the proposed indications for use and no new or differing questions of safety or effectiveness are raised. Therefore, it can be determined that the proposed Rapid^2 Magnetic Stimulators are substantially equivalent to the predicate device.