February 20, 2026

Soterix Medical, Inc.
Abhishek Datta, PhD
CEO/CTO
1480 US Highway 9 North, Suite 204
Woodbridge, New Jersey 07095

Re: K251653
Trade/Device Name: SPRY TMS Therapy System (0550)
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 Dr. Datta:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 and Part 809); 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 D. Scott
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*
K251653

Device Name
SPRY TMS Therapy System (0550)

Indications for Use *(Describe)*
The SPRY TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients, who have failed to achieve 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.

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Traditional 510(k) Application: SPRY TMS Therapy System

510(k) SUMMARY

I. SUBMITTER

Company:Soterix Medical, Inc.
Address: 1480 US 9N, 204, Woodbridge, NJ 07095
Phone: 880-990-8327
Fax: 212-315-3232
Contact Person: Abhishek Datta
Date Prepared: Date of submission: May 29, 2025

II. DEVICE

Proprietary Name: SPRY TMS Therapy System
Common Name: Repetitive Transcranial Magnetic Stimulator
Classification Name: Transcranial Magnetic Stimulator
Product Code: Fax: OBP
Device Class: Class II
Regulation Number: 882.5805
Classification Panel:Neurology

III. PREDICATE DEVICE

ALTMS Magnetic Stimulation Therapy System, K220625

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The SPRY TMS Therapy System is a medical device developed for the treatment of adult patients with Major Depressive Disorder (MDD) who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Transcranial Magnetic Stimulation (TMS) is a non-invasive neuromodulation technique that generates brief, rapidly changing magnetic pulses through a figure-of-eight transducer coil positioned on the scalp. These pulses induce localized electric fields in the cortical tissue, leading to neuronal activation and depolarization, thereby modulating brain activity. The SPRY TMS Therapy System is based on this principle and is intended to target the dorsolateral prefrontal cortex (DLPFC) to alleviate symptoms of Major Depressive Disorder. The device is available by prescription only and must be administered under the supervision of a licensed physician.

The main Components of the SPRY TMS Therapy System include:

1. Stimulator Unit

- Supplies controlled electrical pulses to the transducer coil
- Includes the power supply, high-voltage capacitor charge/discharge circuits, control electronics, and safety monitoring system
- Features a liquid-based cooling mechanism to maintain coil temperature within safe limits during extended operation

2. Transducer
   - Figure-of-eight coil designed to generate a localized magnetic field

3. User Interface
   - Provides a graphical interface for clinicians to set treatment parameters (e.g., frequency, train duration, inter-train interval)
   - Displays real-time system status and safety-related information

V. INDICATIONS FOR USE

The SPRY TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients, who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

The SPRY TMS Therapy System has the same indications for use as the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The SPRY TMS THERAPY SYSTEM demonstrates substantial equivalence to the predicate device in terms of its principal technological characteristics. Both devices are intended for the treatment of adult patients with Major Depressive Disorder who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Accordingly, both devices share the same indications for use.

From a technological standpoint, both systems deliver Transcranial Magnetic Stimulation (TMS) through a stimulator unit, transducer coil, and positioning arm. The treatment procedures, including system setup, patient preparation, motor threshold determination, coil positioning, and patient therapy, are essentially identical. In both devices, rapidly changing magnetic pulses are delivered repetitively to induce localized electric fields in the dorsolateral prefrontal cortex (DLPFC), leading to neuronal depolarization and modulation of neural circuits underlying therapeutic effect.

The SPRY THERAPY SYSTEM and the predicate device differ in certain design specifications, including dimensions, coil parameters, pulse width, and maximum magnetic field strength measured at 2 cm depth. These differences reflect design and operational variations only and remain within the range of legally marketed TMS systems. They do not raise new questions of safety or effectiveness.

Therefore, the SPRY TMS THERAPY SYSTEM is substantially equivalent to the predicate device with respect to intended use, technological characteristics, performance, and clinical effect, and does not raise new questions of safety or effectiveness.

VII. PERFORMANCE DATA

Non-Clinical Test summary

The SPRY TMS THERAPY SYSTEM underwent a series of non-clinical performance evaluations in accordance with the FDA's Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems, including characterization of the magnetic field.

Electrical safety and electromagnetic compatibility (EMC) testing demonstrated compliance with IEC 60601-1 and IEC 60601-1-2 standards. Biocompatibility of patient-contacting components, specifically the transducer, was assessed in accordance with ISO 10993-1, confirming the materials are biocompatible.

Software Verification and Validation testing was conducted in accordance with the FDA software guidance and IEC 62304. The results verified that the software operates as intended and meets the specified requirements.

To establish substantial equivalence with the predicate device, comparative testing was performed on output waveforms, spatial distribution of electric and magnetic fields, and magnetic field gradient characteristics. The results demonstrated that the performance of the subject and predicate devices is substantially equivalent.

In addition, a risk analysis was conducted in accordance with ISO 14971. All identified risks were evaluated and either determined to be acceptable or effectively mitigated through risk control measures. All results met the applicable acceptance criteria.

In conclusion, the SPRY TMS Therapy System was shown to be as safe, effective, and performant as the predicate device.

Clinical Test summary

No new clinical studies were conducted to support this 510(k) submission for the SPRY TMS Therapy System. Non-clinical testing and comprehensive technological comparison demonstrated that the subject device and the predicate device are identical in intended use, target patient population, treatment procedure, treatment location, and standard therapeutic protocol.

The identified differences do not affect safety or effectiveness. Therefore, no new clinical data were deemed necessary to establish substantial equivalence.

Substantial Equivalence Comparison Table

Parameter	SPRY TMS Therapy System (Proposed Device)	ALTMS Magnetic Stimulation Therapy System (Predicate Device)	Comparison

Device Name and Model	SPRY TMS Therapy System	ALTMS Magnetic Stimulation Therapy System (Blossom TMS Therapy System)	–
Manufacturer	REMED Co., Ltd.	REMED Co., Ltd.	–
Indications For Use	SPRY TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients, who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.	ALTMS Magnetic Stimulation Therapy System (also Blossom TMS Therapy System) is indicated for the treatment of Major Depressive Disorder in adult patients, who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.	**Identical**
Parameter	**SPRY TMS Therapy System (Proposed Device)**	**ALTMS Magnetic Stimulation Therapy System (Predicate Device)**	**Comparison**
Classification Name	Transcranial Magnetic Stimulator	Transcranial Magnetic Stimulator	**Identical**
Product Code	OBP	OBP	**Identical**
Regulatory Class	Class II	Class II	**Identical**
Classification Number	882.5805	882.5805	**Identical**
Classification Panel	Neurology	Neurology	**Identical**
Parameter	**SPRY TMS Therapy System (Proposed Device)**	**ALTMS Magnetic Stimulation Therapy System (Predicate Device)**	**Comparison**
Applicator configuration and core material	Biphasic Figure 8 Coil	Biphasic Figure 8 Coil	**Identical**
Pulse Shape	Biphasic The output waveform produced by the biphasic figure 8 coil was measured using a calibrated oscilloscope. As a result, the	Biphasic The output waveform produced by the biphasic figure 8 coil was measured using a calibrated search coil connected to an oscilloscope.	**Identical**

	waveform could be quantified in three directions as well as in time	As a result, the waveform could be quantified in three directions as well as in time.	
Dimensions	Width: 265 mm Length: 200 mm Height: 44.5 mm	Width: 256 mm Length: 188 mm Height: 37 mm	**Note 1** See SE statement
Coil Parameters	Flat spiral winding, UEW 2.0*7.0mm wire, 12 turns/wing*2	Flat spiral winding, AIW 2.0 x 4.0mm wire, 12 turns/wing x 2	**Note 2** See SE statement
Core material	Air	Air	**Identical**
Cooling	Liquid cooled	Liquid cooled	**Identical**
Pulse Train Duration Range (sec)	0.1-1 Hz: 1-1800sec (± 20%) 2-30 Hz: 1-20sec (± 20%)	0.1-1 Hz: 1-1800sec (± 20%) 2-30 Hz: 1-20sec (± 20%)	**Identical**
Inter-train interval range	1-120 sec	1-120sec	**Identical**
Pulse Width (± accuracy)	360 µs (±20%)	430 µs	**Note 3** See SE statement
Amplitude in Standard Motor Threshold (SMT) units	0.3-1.9 SMT	0.3-1.9 SMT	**Identical**
Frequency (± accuracy)	0.1-30 Hz (± 20%)	0.1-30 Hz (± 20%)	**Identical**
Magnetic Field Intensity (Peak Magnetic Energy)	1.0 Tesla (± 20%)	1.0 Tesla (± 20%)	**Identical**
Magnetic Field Strength (T) at coil surface	1.0 Tesla (± 20%)	1.0 Tesla (± 20%)	**Identical**
Pulse Amplitude	2.0 Vp-p at magnetic field	2.0 Vp-p at magnetic field	**Identical**
Spatial distribution of the output level	Refer to sponsor's performance report for the spatial distribution of the output level.	Refer to the sponsor’s test report for the Spatial distribution of the output level by the predicate device ALTMS Magnetic Stimulation	**Refer to report**

	Document Name: "Performance Report_rTMS Special Controls_0550"	Therapy System	
Linearity of the output level	Refer to sponsor's performance report for the linearity of the output level . **Document Name**: "Performance Report_rTMS Special Controls_0550"	Refer to the sponsor's test report for the linearity of the output level by the predicate device ALTMS Magnetic Stimulation Therapy System	**Refer to report**
Magnetic field intensity	120% of the MT	120% of the MT	**Identical**
Number of trains	75	75	**Identical**
Maximum trains per session	120	120	**Identical**
Maximum number of pulses per session (cumulative exposure)	4,800	4,800	**Identical**
Maximum output amplitude (V/m) at a depth of 2cm below the coil surface	150 V/m	150 V/m	**Identical**
Magnetic Field: Peak Magnetic Field Strength at 2cm (in dB/dt)	10kT/s	8.1kT/s	**Note 4** See SE statement
Temperature on Surface at Maximum Output	41°C	41°C	**Identical**
Magnetic field strength ratio	1.8	1.8	**Identical**
Number of Trains	75	75	**Identical**

Magnetic pulses per session	3000	3000	**Identical**
Treatment session duration	18.8 - 37.5 min	18.8 - 37.5 min	**Identical**
Session per week	5	5	**Identical**
Area of the brain to be stimulated	Frontal Cortex	Frontal Cortex	**Identical**
Standard Treatment Protocol			
Inter-train Interval Range	1-120 sec	1-120 sec	**Identical**
Magnetic field intensity	120% of the MT	120% of the MT	**Identical**
Frequency	10Hz	10Hz	**Identical**
Train Duration	4 sec	4 sec	**Identical**
Inter-train Interval	11-26sec	11-26sec	**Identical**
Number of trains	75	75	**Identical**
Magnetic pulses per session	3,000	3,000	**Identical**
Treatment session duration	18.8-37.5 min	18.8-37.5 min	**Identical**
Sessions per week	5	5	**Identical**
Treatment schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	**Identical**

Note 1 - Dimensions:
The SPRY TMS device is slightly larger in size compared to the predicate device; however, this external difference does not affect the core functional performance and therefore does not introduce any new safety concerns. The difference arises solely from mechanical design variations and bench testing verifies substantially equivalent results with respect to output waveform, magnetic field distribution, and magnetic field strength.

Note 2 - Coil Parameter:
Both the SPRY TMS THERAPY SYSTEM and the predicate device use the same planar spiral winding

configuration with identical number of turns. The design differences in conductor type and cross-sectional specifications do not affect the fundamental operating principle or the induced magnetic field characteristics. As a result, there are no new concerns for safety and effectiveness.

Note 3 - Pulse Width:
The SPRY TMS THERAPY SYSTEM delivers a pulse width of 360 μs, while the ALTMS delivers 430 μs. This difference is a design variation and does not impact clinical performance. Although pulse width can shift the motor threshold (MT), stimulation is applied relative to %MT, thereby maintaining equivalent safety and effectiveness.

Note 4 - Magnetic Field: Peak Magnetic Field Strength at 2cm (in dB/dt):
The SPRY TMS THERAPY SYSTEM showed slightly higher magnetic field change rates at both the scalp surface and 2cm depth compared to the predicate device; however, since stimulation intensity is personalized based on each patient's motor threshold (MT) in clinical practice, the absolute differences in dB/dt do not have a substantive impact on clinical safety or efficacy.

VIII. CONCLUSIONS

In conclusion, the SPRY TMS Therapy System is substantially equivalent to the predicate device with respect to intended use, technological characteristics, performance, and clinical effect, and does not raise new questions of safety or effectiveness.

The comprehensive evaluation of the SPRY TMS Therapy System along with the aforementioned design verification and validation testing assessments provide assurance that the SPRY TMS Therapy System has met the pre-determined design requirements per the FDA's recognized consensus standards and special controls guidance document.

The comparative and comprehensive assessments to the predicate device all point to the conclusion that the SPRY TMS Therapy System is substantially equivalent to the stated predicate system.