November 26, 2021

REMED Co., Ltd
Kyungyoon Kang
CEO
K-Biotech
201 South 4th Street, Suite 727
San Jose, California 95112

Re: K202537
Trade/Device Name: ALTMS Magnetic Stimulation Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: October 20, 2021
Received: October 28, 2021

Dear Kyungyoon Kang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202537

Device Name
ALTMS Magnetic Stimulation Therapy System

Indications for Use *(Describe)*
ALTMS Magnetic Stimulation 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.

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

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510(k) Summary

Pursuant to Section 510(k) of Chapter V of the Federal Food, Drug, and Cosmetic Act and in accordance with subpart E of Part 807, Title 21 of the Code of Federal Regulations, REMED Co., Ltd. submits the following information as premarket notification for the proposed device ALTMS Magnetic Stimulation Therapy System.

I. SUBMITTER

- Company: REMED Co., Ltd.
- Address: #301-#303 Migun Techno World II, 187, Techno 2-Ro, Yuseong-gu, Daejeon, Republic of Korea, Postal code: 34025
- Tel: 82-42-934-5560
- Fax: 82-42-934-5562
- 510(k) Number: K202537

510(k) Correspondent: Seong Hyeon Kim, Manager K-Bio Solutions
sarah.kim@kbiotechsolutions.com
Tel: 82-2-597-2700, USA: 408-750-7843

Date Prepared: November 22nd, 2021

II. PROPOSED DEVICE

- Type of Submission: Traditional Premarket Notification
- Trade Name of Device: ALTMS Magnetic Stimulation Therapy System
- Classification Name of Device: Repetitive Transcranial Magnetic Stimulation System
- Review Panel: Neurology
- Regulation Number: 21 CFR 882.5805
- Regulatory Class: Class II
- Product Code: OBP

III. PREDICATE DEVICE

Rapid^2 Therapy System (K143531, Manufacturer: Magstim Company Limited)
The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The ALTMS Magnetic Stimulation Therapy System is a computerized, electromechanical medical device that generates and delivers non-invasive, magnetic stimulation using brief duration rapidly alternating, or pulsed, magnetic

fields to induce electrical currents directed at spatially discrete regions of the cerebral cortex. This method of cortical stimulation by application of brief magnetic pulses to the head is known as Transcranial Magnetic Stimulation.

The ALTMS Magnetic Stimulation Therapy System is substantially equivalent to the predicate device, Rapid^2 Therapy System (K143531, Manufacturer: Magstim Company Limited). The intended use and indications for use of the proposed device are identical to the predicate device. Both devices are clinically operated based on the same course of the device use including the TMS system set up, patient preparation process, determination of patient's motor threshold, coil position, and treatment administration at the predetermined treatment stimulation parameters.

The ALTMS Magnetic Stimulation Therapy System is a non-invasive tool for the stimulation of cortical neurons for the treatment of Major Depressive Disorder in audit patients, who have failed to achieve satisfactory improvement from antidepressant medication in the current episode. The ALTMS Magnetic Stimulation Therapy System is used for patient treatment by prescription only under the supervision of a licensed physician. The proposed device can be used in both inpatient and outpatient settings, including physicians' offices, hospitals, and clinics. The ALTMS Magnetic Stimulation Therapy System is an integrated system consisting of a combination of hardware, software, and accessories. It includes a Mobile console which houses the electronic components, provides mechanical support for the ferromagnetic Treatment Coil. The Standing Arm, an accessory device included in the ALTMS provides the coil positioning function.

V. INDICATIONS FOR USE

ALTMS Magnetic Stimulation 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed, ALTMS Magnetic Stimulation Therapy System and predicate device, Rapid^2 Therapy System (K143531) share the same intended use and indications for use. The actual substance and essential scopes of the intended use and indications for use between the ALTMS Magnetic Stimulation Therapy System and predicate device are substantially equivalent.

Few minor differences between the proposed and predicate devices are primarily identified through dimensional differences in modest levels, which are not considered to raise different questions of safety and effectiveness compared to the predicate device. The favorable results of the design verification and electrical safety testing of the ALTMS Magnetic Stimulation Therapy System have demonstrated that the proposed device has met the predetermined design requirements and the FDA's recognized standards, including the electrical safety and performance standards and EMC standards as the predicate device. The design and function of the ALTMS Magnetic Stimulation Therapy System do not involve a new or different technological principle that would be considered to raise different questions in safety and effectiveness compared to the predicate device. The principle of operation, critical function and clinical use and applicatio are the same as the predicate device, Rapid^2 Therapy System (K143531).

VII. SAFETY & PERFORMANCE DATA

The following safety and performance data were provided in support of this substantial equivalence determination.

- **Biocompatibility Testing**

In order to meet the FDA's consensus standards for biocompatibility requirements identified in the FDA Guidance titled, "Use of ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing within a Risk Management Process (Issued June 16, 2016)", GLP biocompatibility testing of the proposed, ALTMS Magnetic Stimulation Therapy System has been completed with the favorable results.

Our biocompatibility risk assessments of the ALTMS Magnetic Stimulation Therapy System have concluded that it is warranted no additional biocompatibility testing of the proposed device is necessary.

Biocompatibility Testing Evaluations of ALTMS Magnetic Stimulation Therapy System Per ISO 10993 and FDA Guidance (June 16, 2016):

- Cytotoxicity
- Repeated Patch Dermal Sensitization Test
  (GLP - Buehler Method Modified for Medical Devices)
- ISO Primary Skin Irritation Test

➢ Design Verification and Validation Testing

Design Verification and Validation (DV&V) testing was performed to verify that the proposed ALTMS Magnetic Stimulation Therapy System meets the predefined safety and performance requirements. Testing was also conducted to verify the effectiveness of the implemented risk control measures to mitigate the risks identified within the risk management process (per ISO 14971:2012, Medical Devices - Application of Risk Management to Medical Devices). The following design verification, or performance testing of ALTMS Magnetic Stimulation Therapy System have been completed with the favorable test results, meeting the applicable ISO standards and FDA's recognized consensus standards related to evaluation of performance of ALTMS Magnetic Stimulation Therapy System.

The favorable results of the design verification and validation tests have demonstrated that the design output of the proposed ALTMS Magnetic Stimulation Therapy System matches its design input and is appropriate to be used for the intended use, which support its substantially equivalent profile to the predicate device. The following design verification, validation, electrical safety and performance testing of the ALTMS Magnetic Stimulation Therapy System have been comprehensively completed with the favorable test results:

Design Verification Performed (Safety and Performance Testing)

- ALTMS Magnetic Stimulation Therapy System Test

IEC Electrical Safety and Performance Testing

- IEC 60601-1
- IEC 60601-1-6
- IEC 60601-1-2
- IEC 61000-3-2
- IEC 61000-3-3
- IEC 61000-4-2
- IEC 61000-4-3
- IEC 61000-4-4
- IEC 61000-4-5
- IEC 61000-4-6
- IEC 61000-4-8
- IEC 61000-4-11
- IEC 62366

Software Verification and Validation Testing

Shipping Validation Test

The results of the shipping validation test of Talent-Pro Electromagnetic Stimulator demonstrate that the proposed, ALTMS Magnetic Stimulation Therapy System which is equivalent to Talent-Pro Electromagnetic Stimulator in size and weight has met all the pre-determined shipping validation test requirements.

Substantial Equivalence Comparison

DESCRIPTIVE INFORMATION	Proposed device: ALTMS Magnetic Stimulation Therapy System (K202537)	Predicate device: Rapid² Therapy System (K143531)
Pulse Shape	The output waveform produced by the biphasic figure 8 coil was measured using a calibrated search coil connected to an oscilloscope. As a result, the waveform could be quantified in three directions as well as in time.	The output waveform produced by the biphasic figure 8 coil was measured using a calibrated search coil connected to an oscilloscope. As a result, the waveform could be quantified in three directions as well as in time.
Pulse Train Duration Range (sec)	Pulse train durations range 0.1~1 Hz: 1~1800sec 2~30 Hz: 1~20sec Inter-train interval range 1~120sec	Pulse train durations range 1~20sec Inter-train interval range 10~60sec
Pulse Width	430 µs	300µs
Pulse Amplitude	2.76V Pk-Pk at peaking coil	N/A
Spatial distribution of the output level	Refer to the sponsor's test report for the Spatial distribution of the output level by the proposed device ALTMS Magnetic Stimulation Therapy System.	Refer to the subject test report for the Spatial distribution of the output level by the predicate device Rapid²Therapy System.

Linearity of the output level	Refer to the sponsor's test report for the linearity of the output level by the proposed device ALTMS Magnetic Stimulation Therapy System.	Refer to the subject test report for the linearity of the output level by the predicate device Rapid^2 Therapy System.
Magnetic field intensity	120% of the MT	120% of the MT
Number of trains	75	75
Magnetic pulses per session	3000	3000
Treatment session duration	37.5 min	37.5 min
Sessions per week	5	5
Area if the brain to be stimulated	Frontal Cortex	Frontal Cortex
Applicator configuration and core material	Biphasic Figure 8 Coil	Biphasic Figure 8 Coil
Coil Parameters	Flat spiral winding, AIW 2.0 x 4.0mm wire, 12 turns/wing x 2	Flat spiral winding WC = 1.0 × 3.5 mm wire N = 3x19 turns/wing × 2 wings
Maximum trains per session	120	140
Temperature on Surface at Maximum Output	41°C	41°C
Magnetic Field: Peak Magnetic Field Strength at 2cm (in dB/dt)	8.1kT/s	N/A
Machine Output Stimulation Parameters, with Amplitude in SMT Units	0.3-1.9 SMT	0.28-1.9 SMT

VIII. CONCLUSIONS

In conclusion, the critical aspects of the ALTMS Magnetic Stimulation Therapy System are substantially equivalent to the predicate device Rapid^2 Therapy System (K143531). The proposed ALTMS Magnetic Stimulation Therapy System shares the same intended use, indications for use and operation principle as the predicate device, Rapid^2 Therapy System (K143531). The technological characteristics of the ALTMS Magnetic Stimulation Therapy System are similar to the predicate and the minor differences are assessed not to raise different questions in terms of safety and effectiveness. The comprehensive evaluations of the ALTMS magnetic Stimulation Therapy System along with the aforementioned design verification and validation testing assessments provide assurance that the ALTMS Magnetic Stimulation Therapy System has met the predetermined design requirements per the FDA's recognized consensus standards or manufacturer's standards which have been applied to the predicate devices in the same manner. The comparative assessments all point to the conclusion that the ALTMS Magnetic Stimulation Therapy System is substantially equivalent to the predicate, Rapid^2 Therapy System (K143531).