April 6, 2022

REMED Co., Ltd
Soojung Moon
CEO
Allura Medical Solutions Inc.
5485 Rathdrum Way
Antioch, California 94531

Re: K220625
Trade/Device Name: ALTMS Magnetic Stimulation Therapy System, Blossom TMS Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: March 2, 2022
Received: March 3, 2022

Dear Soojung Moon:

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
Neuromodulation Psychiatry Devices
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)*
K220625

Device Name
ALTMS Magnetic Stimulation Therapy System (also Blossom TMS Therapy System)

Indications for Use *(Describe)*
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.

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

I. Submitter Information

Company:	REMED Co., Ltd.
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Tel / Fax:	+82-42-934-5560 / +82-42-934-5562
Contact Person:	S.J. Moon, Official correspondent of REMED Co., Ltd. +1 (407) 242 9793 / sjmoon@allurameds.com
Date of submission:	Date of submission: March 2nd, 2022

II. Device Information

Proprietary Name(s):	ALTMS Magnetic Stimulation Therapy System (Blossom TMS Therapy System)
Common Name:	Repetitive Transcranial Magnetic Stimulator
Classification Name:	Transcranial Magnetic Stimulator
Product Code:	OBP
Device Class:	Class II
Regulation Number:	882.5805
Classification Panel:	Neurology

III. Predicate Information

- ALTMS Magnetic Stimulation Therapy System (REDMED Co., Ltd. K202537) – Primary predicate device
- Neurosoft TMS (TeleEMG, LLC. K173441) – Reference device

IV. Device Description

The ALTMS Magnetic Stimulation Therapy System (also Blossom TMS 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 (also Blossom TMS Therapy System) is substantially equivalent to the predicate device, our own ALTMS Magnetic Stimulation Therapy System (K202537) and Neurosoft TMS (K173441). 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, and determination of patient's motor threshold, coil position, and treatment administration at the predetermined treatment stimulation parameters.

The ALTMS Magnetic Stimulation Therapy System (also Blossom TMS 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 (also Blossom TMS 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 (also Blossom TMS Therapy System) is an integrated system consisting of a combination of hardware, software, and accessories. The Standing Arm, an accessory device included in the ALTMS Magnetic Stimulation Therapy System (also Blossom TMS Therapy System) provides the coil positioning function.

V. Indication for Use

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.

VI. Comparison of Indications for Use Statements and Technological Characteristics

The ALTMS Magnetic Stimulation Therapy System (also Blossom TMS Therapy System) is substantially equivalent to the predicate devices (our own ALTMS Magnetic Stimulation Therapy System and Neurosoft TMS). The ALTMS Magnetic Stimulation Therapy System (also Blossom TMS Therapy System) and the predicate devices have identical intended use / indication for use, and technological characteristics. The principles of operation, the output stimulation parameters and the materials are equivalent to the predicates. The modification to the device allows a range of inter-train intervals from 11 to 26 seconds, rather than the fixed 26 second duration, which will allow a reduction in treatment time from 37.5 minutes to a minimum of 18.8 minutes.

The proposed, ALTMS Magnetic Stimulation Therapy System (also Blossom TMS Therapy System) and predicate device, our own ALTMS Magnetic Stimulation Therapy System (K202537) and Neurosoft TMS (K173441) 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 (also Blossom TMS 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 (also Blossom TMS 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 (also Blossom TMS 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 application are the same as the predicate device, our own ALTMS Magnetic Stimulation Therapy System (K202537) and Neurosoft TMS (K173441).

VII. Safety & Performance

Electrical safety and performance testing have been successfully carried out in accordance with IEC 60601, IEC 61000, and IEC 62366. Additionally, biocompatibility test also has been successfully fulfilled following ISO 10993-1. All the results already demonstrated through the primary predicate device, ALTMS Magnetic Stimulation Therapy System (K202537), and there is no change of the proposed device from the primary predicate device. The minor change to indicate the treatment protocols on the IFU has been evaluated by the risk analysis procedure. Therefore, the proposed device, ALTMS Magnetic Stimulation Therapy System(also Blossom TMS Therapy System), is as safe and effective as the reference device, which meet user's needs, and the Instruction For Use (IFU) support the safe and effective use of the proposed device.

Substantial Equivalence Comparison

DESCRIPTIVE INVORMATION	Proposed Device: ALTMS Magnetic Stimulation Therapy	Predicate Device: ALTMS Magnetic Stimulation Therapy System (K202537)	Predicate Device: Neurosoft TMS (K173441)

	System (also Blossom TMS Therapy System)		
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.	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)	0.1~1 Hz: 1~1800sec 2~30 Hz: 1~20sec	0.1~1 Hz: 1~1800sec 2~30 Hz: 1~20sec	0.5~100 (sec)
Inter-train interval range	1~120sec	1~120sec	0~300 (sec)
Pulse Width	430 μs	430 μs	280μS
Pulse Amplitude	2.76V Pk-Pk at peaking coil	2.76V Pk-Pk at peaking coil	Unknown
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 sponsor's test report for the Spatial distribution of the output level by the proposed device ALTMS Magnetic Stimulation Therapy System.	Unknown
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 sponsor's test report for the linearity of the output level by the proposed device ALTMS Magnetic Stimulation Therapy System.	Unknown
Magnetic field intensity	120% of the MT	120% of the MT	120% of the MT
Number of trains	75	75	75
Magnetic pulses per session	3000	3000	3000
Treatment session duration	18.8 - 37.5 min	37.5 min	18.8 min - 37.5 min

Sessions per week	5	5	5
Area if the brain to be stimulated	Frontal Cortex area	Frontal Cortex area	Frontal Cortex area
Applicator configuration and core material	Biphasic Figure 8 Coil	Biphasic Figure 8 Coil	Figure 8 Coil
Coil Parameters	Flat spiral winding, AIW 2.0 x 4.0mm wire, 12 turns/wing x 2	Flat spiral winding, AIW 2.0 x 4.0mm wire, 12 turns/wing x 2	FEC-02-100C Inner diameter: 47x50mm[1] Outer diameter: 97x100mm[1] Area: 184725mm[2] Average Inductance: 10µH Flat spiral winding N: 16 turns (2 layers x 2 wings) AFEC-02-100C Inner diameter: 36x51mm[1] Outer diameter: 84x106mm[1] Area: 184725mm[2] Average Inductance: 10µH Flat spiral winding N: 16 turns (2 layers x 2 wings) FEC-02-100 Inner diameter: 47x50mm[1] Outer diameter: 97x100mm[1] Area: 91560mm[2] Average Inductance: 10µH Flat spiral winding N: 16 turns (2 layers x 2 wings) AFEC-02-100 Inner diameter: 36x51mm[1]

			Outer diameter: 84x106mm[1] Area: 87200mm[2] Average Inductance: 10μH Flat spiral winding N: 16 turns (2 layers x 2 wings)
Maximum trains per session	120	120	4800
Temperature on Surface at Maximum Output	41°C	41°C	41°C
Magnetic Field: Peak Magnetic Field Strength at 2cm (in dB/dt)	8.1kT/s	8.1kT/s	Unknown
Machine Output Stimulation Parameters, with Amplitude in SMT Units	0.3-1.9 SMT	0.3-1.9 SMT	FEC-02-100-C: 0 - 1.89 AFEC-02-100-C: 0 - 2.38 FEC-02-100: 0 - 1.92 AFEC-02-100: 0 - 2.33

VIII. Conclusion

In conclusion, the critical aspects of the ALTMS magnetic Stimulation Therapy System (also Blossom TMS Therapy System) are the same as the predicate devices, Neurosoft TMS (K173441) and to our own ALTMS Magnetic Stimulation Therapy System (K202537) including the intended use, indications for use, operation principle. The comprehensive evaluations of the ALTMS magnetic Stimulation Therapy System (also Blossom TMS Therapy System) along with the aforementioned design verification and validation testing assessments provide assurance that the ALTMS magnetic Stimulation Therapy System (also Blossom TMS Therapy System) has met the predetermined design requirements per the FDA's recognized consensus standards or manufacturer's standards applied to the predicate devices in the same manner. The comparative and comprehensive assessments all point to the conclusion that the ALTMS magnetic Stimulation Therapy System (also Blossom TMS Therapy System) is substantially equivalent to the predicate, Neurosoft TMS and to our own ALTMS Magnetic Stimulation Therapy System.