February 17, 2019

Axilum Robotics
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K182768
Trade/Device Name: TMS-Cobot TS MV
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: QFF
Dated: January 18, 2019
Received: January 18, 2019

Dear Janice Hogan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182768

Device Name
TMS-Cobot TS MV

Indications for Use *(Describe)*
Axilum Robotics TMS-Cobot TS MV is a computer controlled electromechanical arm indicated for spatial positioning and orientation of the treatment coil of the MagVita TMS Therapy System

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
K182768
Axilum Robotics' TMS-Cobot TS MV

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Date Prepared: September 28, 2018

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Name of Device: TMS-Cobot TS MV

Common or Usual Name: Electromechanical arm for transcranial magnetic stimulation system

Classification Name: 21 CFR 882.5805, Repetitive Transcranial Magnetic Stimulation System

Regulatory Class: Class II

Product Code: QFF

Predicate Devices
MagVita TMS Therapy System (K150641)

Reference Devices
Medtech SA ROSA Spine (K151511)

Device Description
Axilum Robotics TMS-Cobot TS MV is a computer controlled electromechanical arm based on collaborative robotics technology, providing guidance for the positioning and orientation of a Transcranial Magnetic Stimulation (TMS) coil - connected to its stimulator - under the supervision of an optical tracking system.

Axilum Robotics TMS-Cobot TS MV comprises the electromechanical collaborative arm on its cart, its optical tracking system, with its software, 3D camera and a coil adaption kit with its mechanical adaptor, to fix the coil on the robotic arm, as well as a contact sensor.

The device is intended to be used in combination with the TMS stimulator, treatment coil and treatment chair from the previously-cleared MagVenture MagVita system.

Intended Use / Indications for Use
Axilum Robotics TMS-Cobot TS MV is a computer controlled electromechanical arm indicated for spatial positioning and orientation of the treatment coil of the MagVita TMS Therapy System.

Summary of Technological Characteristics
The TMS-Cobot TS MV is an accessory to the predicate MagVita TMS Therapy System (K150641). The MagVita TMS Therapy System contains a component intended to position the treatment coil called the Super Flexible Arm. The TMS-Cobot TS MV can be utilized in place of the Super Flexible Arm along with the other components of the MagVita TMS Therapy System.

The company believes that the TMS-Cobot TS MV does not present any new unique risks compared to the MagVita system, and that accurate coil positioning is key for both systems. The general risks of contacting the patient's head or mispositioning the coil are risks that are common to both manual and robotically controlled arms:

The use of robotic arms to position tools such as surgical instruments is not novel, see for example, the Medtech SA ROSA Spine device (K151511). Both the TMS-Cobot TS MV and the ROSA Spine are electromechanical arms intended to assist physicians in the spatial positioning and orientation of instrument holders. The TMS-Cobot TS MV and the ROSA Spine both contain a hardware structure that supports the electromechanical arm, along with a holder for the coil or instruments. Recording for both the TMS-Cobot TS MV and the ROSA Spine utilize fiducial markers and an optical registration device.

Substantial Equivalence comparison

Feature	**MagVita TMS Therapy System with Super Flexible Arm (alone)** **K150641 (Predicate)**	**MagVita TMS Therapy System using Axilum Robotics TMS-Cobot TS MV in lieu of Super Flexible Arm** **K182768 (Subject)**
Indications for Use	The MagVita TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode	Axilum Robotics TMS-Cobot TS MV is a computer controlled electromechanical arm indicated for spatial positioning and orientation of the treatment coil of the MagVita TMS Therapy System *

Intended use of Electromechanical arm	N/A	Axilum Robotics TMS-Cobot TS MV is a computer controlled electromechanical arm indicated for spatial positioning and orientation of the treatment coil of the MagVita TMS Therapy System.
Coil holder	Passive mechanical arm	Active electromechanical arm
Joints	3	6
Degrees of freedom	6	6
Coil holder	Coil handle is directly tightened in the tip of the articulated arm	Coil is attached to the robotic arm via a coil adapter fixed to the coil
Coil holder material	Aluminum	Aluminum
Position of coil holder	Mobile, attached to stimulator wheel cart or (optionally) either to the back of the treatment chair or to a table.	Mobile, mounted on a wheel cart
Piloting system	Human pilot manually acting on the articulated arm	Human pilot through the free-drive mode, and: 3D tracking system
Coil for depression treatment	Cool-B65 coil	Cool-B65-RO coil which is the robotic adaptation of Cool-B65 coil.
Patient chair	Included, FDA-cleared	Can use the chair included in MagVita system
Coil positioning strategy	Guided by user via anatomical landmarks on the head (no MRI imaging prior to treatment)	With 3D tracking system: guided by user via anatomical landmarks on the head (no MRI imaging prior to treatment), and fine-tuning from the control panel.
Coil to head contact management	None, user-managed contact from visual observation of coil and head	From measurements of a contact sensor added to the treatment side of the coil
Head motion compensation	User-managed from visual observation of the patient and acting on the articulated stand	Robot-automated, from real-time camera measurements. In addition, user can activate the free-drive mode and manually re-adjust the position; Or, user can use the device's control panel to fine tune the position and orientation of the coil

Collision management	None (user-managed while acting on the knob of the articulated stand)	Collaborative robotics technology allows for collision detection at each joint level in addition to coil contact sensor level

*Although the IFU of the subject device is different than the IFU of the predicate device the subject device is an accessory to the system and its intended use is identical to the intended use of the passive mechanical arm of the predicate device.

Performance Data

TMS-Cobot TS MV was tested to the following standards:

- AAMI ANSI ES 60601-1:2005/(R)2012 And A1:2012Electromedical devices - Part 1: general requirements for basic safety and essential performances
- IEC 60601-1-2: 2014, Edition 4.0, Electromedical devices - Part 1.2: general requirements for basic safety and essential performances. Collateral Standard: Electromagnetic Disturbances - Requirements and Testing

The nonclinical testing completed for the TMS-Cobot TS MV included three major categories of testing:

1. **Technical tests**, which include: internal hardware, firmware and software component tests, tests of the software communication protocol used between the various firmware and software components, packaging tests and labeling tests. Software verification and validation for firmware and software components of the device have been tested against their specifications and according to IEC 62304:2015.

2. **Functional tests**, which include integrated product testing using the tracking system and TMS coil that have been designed to verify key aspects of performance of the system such as accuracy, repeatability, operation of the robotic arm's freedrive mode and ability to provide sufficient head motion compensation. Moreover, usability testing was conducted on the device according to IEC 62366:2015 and FDA Guidance document Applying Human Factors and Usability Engineering to Medical Devices.

3. **Compatibility tests**, which verify that the TMS-Cobot TS MV can operate safely with both the treatment coil and the patient seat of the MagVita TMS Therapy System. Particularly, accessibility of the patient's head inside the robotic arm's workspace has been checked to be compatible with the range of patient positions permitted by the patient seat included in MagVita TMS Therapy System.

Robot controller firmware features have been validated in accordance with EN 62304:2006 and FDA's Guidance for General Principles of Software Validation.

Conclusions

The TMS-Cobot TS MV used in combination with the MagVita TMS Therapy System is as safe and effective as the MagVita TMS Therapy System (K150641) alone. The TMS-Cobot TS MV has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the TMS-Cobot TS MV and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the TMS-Cobot TS MV

is as safe and effective as the MagVita TMS Therapy System. Thus, the TMS-Cobot TS MV is substantially equivalent.