August 4, 2023

Levita Magnetics International Corp.
% Cindy Domecus, RAC (US & EU)
Principal, Domecus Consulting Services LLC
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsboroguh, California 94010

Re: K223673
Trade/Device Name: Levita Magnetics Dual Robotic Arm Accessory
Regulation Number: 21 CFR 878.4815
Regulation Name: Magnetic Surgical Instrument System
Regulatory Class: Class II
Product Code: PNL
Dated: June 30, 2023
Received: July 3, 2023

Dear Cindy Domecus,:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2023.08.04 11:55:36 -04'00'

For Mark Trumbore
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K223673

Device Name
Surgeon Controlled Arm

Indications for Use *(Describe)*
The Surgeon Controlled Arm is indicated for use to hold and position a rigid laparoscope/endoscope and the Magnetic Controller of the Levita Magnetic Surgical System in minimally invasive interventions where the Levita Magnetic Surgical System is indicated for use.

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

This summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Applicant Information:

Levita Magnetics International Corporation
4055-A Campbell Avenue
Menlo Park, CA 94025
Alberto Rodriguez-Navarro, MD
CEO and Founder
(650)-241-0320

Contact Person:

Cindy Domecus, R.A.C (US & EU)
Principal, Domecus Consulting Services LLC
Cindy@DomecusConsulting.com

Device Information:

Trade Name:	Surgeon Controlled Arm
Common Name:	Magnetic Surgical System
Classification Name:	Magnetic Surgical Instrument System (21CFR 878.4815)
Device Class:	II
Product Code:	PNL (Magnetic Surgical System)

Predicate Device:

K171947, AKTORmed GmbH SOLOASSIST II

Date Prepared:

June 30, 2023

Device Description:

The Surgeon Controlled Arm for the Levita Magnetic Surgical System (MSS) comprises two collaborative surgeon-controlled arms, which along with their controllers, control software, and custom attachments, are intended to hold and control the Magnetic Controller of the commercially available MSS (most recently cleared under K191762) using an arm and to hold and control a commercially available endoscope with camera using the second arm. The design of the surgeon-controlled arms, referred to as the Scope Arm and the Magnet Arm, includes several redundant safety features that make them well suited for use with the MSS in the operating room environment, including hardware and software safety controls.

When mounted on the Scope Arm, an endoscope can be pivoted and translated as controlled by the user, while maintaining minimal motion at the point where the endoscope enters the patient's body via a standard trocar. Similarly, when mounted on the Magnet Arm, the Magnetic Controller can be moved to different positions on or away from the abdominal wall.

The Surgeon Controlled Arm includes the following components:

(1) Two Carts, which are the Scope Cart and the Magnet Cart. Each Cart includes a surgeon-controlled arm mounted on top of a moveable cart with custom attachments. One arm functions as a Scope Arm to hold a commercially available endoscope with endoscopic camera. The other arm functions as a Magnet Arm and includes a Magnet Holder to hold the Magnetic Controller of the MSS;
(2) a Scope Holder for attachment and detachment of a compatible commercially-available endoscope to the end of the Scope Arm;
(3) a Foot Controller for foot-actuated selection of the active arm and foot-actuated remote control for one of the arms at a time;
(4) custom-programmed software, the Levita Custom Control Software Program.

The Surgeon Controlled Arm provides for computer control of a dual- arm device with motorized axes to hold and control the movements of a rigid endoscope and the Magnetic Controller of the Levita MSS during the minimally-invasive procedures cleared for the MSS (most recently cleared under K191762). The user selects the active arm and controls its movement using a Foot Controller. Only one arm is enabled for computer-controlled movement at any given time; while one arm is being moved, the other arm remains stationary. The user may also manually move the arms (i.e. hand guiding) at any time without the use of the Foot Controller.

For the Scope Arm, the reference point for scope movement is established as the Trocar Point and is set by the user, who positions the endoscope near the trocar inserted in the body opening (e.g. the abdominal fascial layer) and presses the Teach Trocar button on the Scope Adaptor. The Custom Control Software Program then calculates the required individual movements of the Scope Arm motorized axes relative to the Trocar Point in order to achieve the desired total movement of the endoscope with respect to the endoscope view. Once the Custom Control Software Program completes the Teach Trocar procedure, the Foot Controller is enabled, allowing the user in a standing position by the operating table to direct endoscope movement by using their foot to press on switches corresponding to the allowed movement directions.

For the Magnet Arm, the same arm hardware, software, and Foot Controller are employed to move the Magnetic Controller also in the same directions.

Indications for Use:

The Surgeon Controlled Arm is indicated for use to hold and position a rigid laparoscope/endoscope and the Magnetic Controller of the Levita Magnetic Surgical System in

minimally invasive interventions where the Levita Magnetic Surgical System is indicated for use.

Comparison of Intended Use and Technological Characteristics with the Predicate Device:

The subject and predicate devices have the same intended use. Both devices are surgeon-controlled computer-driven systems whose function is to hold and position a rigid laparoscope/ endoscope. The subject device is only indicated for use with the Levita Magnetics Surgical System (most recently cleared under K191762).

The technological characteristics of the subject device and predicate device are substantially equivalent. Both devices have the same principles of operation using similar components: they provide software-based control of surgeon-controlled arm device(s) with motorized axes to hold and move a rigid commercially-available endoscope during minimally-invasive procedures. The user drives the electrically-powered device using a remote controller. The starting point of the movement for each case is saved as the trocar point from which the software calculates the required individual movements of the device arm's motorized axes to achieve the desired total movement. The user may also move the arm by hand guiding, without use of the remote controller. Neither predicate nor subject device interacts directly with any intra-cavity organ, but instead, holds instruments externally.

The following are differences in technological characteristics:

- Both devices include a surgeon-controlled arm for controlling a rigid commercially-available endoscope. The subject device additionally includes a second, similar arm for controlling the Levita Magnetics Magnetic Controller component of the Levita Magnetics Surgical System
- The predicate device remote controller is controlled by hand and the subject device remote controller is controlled by foot.
- The subject device additionally includes a switch to allow the surgeon to determine the active arm for remote control.
- The arm motion control specifications for the subject device, i.e. maximum velocities and acceleration, latency, range of motion, and safety limits, may differ from those of the predicate device, which are unknown.

Performance Data:

The following performance data were provided to demonstrate safety and effectiveness in support of substantial equivalence determination:

- **Electrical safety and electromagnetic compatibility (EMC)** performed to applicable requirements of IEC 60601-1 and IEC 60601-1-2.
- **Software Verification and Validation Testing** were conducted and documentation was provided as recommended by FDA guidance document, "Guidance for the Content of

Premarket Submissions for Software Contained in Medical Devices", issued May 11, 2005. The software for this device was considered as a "Moderate" level of concern. The DRAA complies with the IEC 62366 standard and the IEC 62304.

- **Bench/ Mechanical Testing** was conducted to verify the device meets functional requirements and included the following:
  - Cart stability
  - Strength of the Magnet Holder attachment to the Magnetic Controller
  - Release force of the Magnet Holder latching mechanism
  - Magnetic field strength.
  - Force to engage/disengage the Scope Holder with the Scope Post
  - Strength of the Scope Holder to Scope Post engagement
  - Actuation force for Scope Holder locking mechanism
  - Strength of Scope Holder locking mechanism
  - Durability of attachments
  - Forces to activate switches and pedals
  - Tensile strength of the Foot Controller cable
  - Integrity of the Foot Controller after drop
  - Maximum linear and angular velocities of arm motion
  - Maximum linear and angular accelerations of arm motion
  - Latency of arm motion
  - Range of arm motion
  - Safety limits of arm motion
- **Simulated Use/ Design Validation Testing** of the DRAA was conducted by three surgeons who perform laparoscopic surgery, representing the intended user, to demonstrate the device specifications for the DRAA conform with the intended use and user needs.
- **Cybersecurity risk assessment** was conducted in accordance with FDA guidance document, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", issued October 2, 2014.
- **Sterilization, disinfection, and cleaning process validations** were completed in accordance with FDA guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", issued March 17, 2015.
- **Human factors testing** was conducted on the DRAA according to FDA guidance document, "Applying Human Factors and Usability Engineering to Medical Devices", issued on February 3, 2016. Testing conducted with 30 testers representing intended users. The test was performed successfully. No unexpected device-related events occurred during the Human Factors Validation Testing.

Summary:

The Surgeon Controlled Arm has the same intended use as the predicate device. In addition, it has similar technological characteristics; performance data demonstrates that any differences in technological characteristics do not raise different questions of safety or effectiveness. Therefore, the Surgeon Controlled Arm is substantially equivalent to the cleared predicate device.