April 29, 2019

Levita Magnetics International Corp.
% Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
Domecus Consulting Services, LLC
1171 Barroilhet Drive
Hillsborough, CA 94010

Re: K190006
Trade/Device Name: Levita Magnetic Surgical System
Regulation Number: 21 CFR§ 878.4815
Regulation Name: Magnetic Surgical Instrument System
Regulatory Class: II
Product Code: PNL
Dated: March 27, 2019
Received: March 28, 2019

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 and Part 809); 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,

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K190006

Device Name
Levita Magnetic Surgical System

Indications for Use *(Describe)*
The Levita Magnetic Surgical System is designed to grasp and retract the body and the fundus of the gallbladder in laparoscopic cholecystectomy procedures, the liver in bariatric procedures, and the prostate and periprostatic tissue in prostatectomy procedures to facilitate access and visualization of the surgical site. The device is indicated for use in patients with a BMI range of 20-60 kg/m2.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

510(k) Owner Information:

Levita Magnetics International Corp.
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Phone: 650-241-0320
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Submission Correspondent:

Cindy Domecus, R.A.C. (US & EU)
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Regulatory Consultant to Levita Magnetics
Email: domecusconsulting@comcast.net
Phone: (650) 343-4813

Device Information:

Trade Name:	Levita Magnetic Surgical System
Common Name:	Magnetic Surgical System
Regulation:	21 CFR 878.4815
Regulation Name:	Magnetic Surgical Instrument System
Device Class:	II
Product Code:	PNL

Predicate Devices:

Levita Magnetic Surgical System, K180894 (primary predicate)
Levita Magnetic Surgical System, DEN150007 (secondary predicate)

Date Prepared:

April 26, 2019

Device Description:

The Levita Magnetic Surgical System is composed of two hand-held instruments, the Magnetic Grasper and external Magnetic Controller.

The Magnetic Grasper (sterile, single use), comprised of a distal detachable Grasper Tip attached to a Shaft with handle, is actuated via its pistol-grip handle with two distinct scissor-type motions to open and close the detachable Grasper Tip jaws. Once the Magnetic Grasper is inserted through a compatible

≥ 10 mm laparoscopic port and the Grasper Tip is attached to the desired tissue, the Grasper Tip can be detached from the Shaft and controlled externally using the Magnetic Controller. Traction of the tissue is maintained through the magnetic field attraction between the Grasper Tip and the Magnetic Controller.

The Magnetic Controller (non-sterile, reusable) is a single unit with handles that is held external to the body and emits a magnetic field that attracts the Grasper Tip. Once the Grasper Tip is attached to the desired tissue and detached from the Shaft, the Magnetic Controller is placed external to the body to magnetically attract the Grasper Tip to manipulate the target tissue. Adjusting the distance between the Magnetic Controller and the Grasper Tip will modulate the magnetic attraction used for tissue retraction/mobilization. If desired, the user can connect the Magnetic Controller to a commercially available surgical support arm that is compatible with its arm mount.

Indications for Use:

The Magnetic Surgical System is designed to grasp and retract the body and the fundus of the gallbladder in laparoscopic cholecystectomy procedures, the liver in bariatric procedures, and the prostate and periprostatic tissue in prostatectomy procedures to facilitate access and visualization of the surgical site. The device is indicated for use in patients with a BMI range of 20-60 kg/m^2.

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

The subject and the predicate devices are identical in technological characteristics. The subject device differs from the predicate device by only a modification to the Indications for Use and the associated changes to the labeling. Results of clinical testing demonstrated that the differences in the indications for use do not raise different questions of safety and effectiveness, and, therefore, the subject device has the same intended use as the predicate device.

Comparison of Intended Use and Indications for Use

	Subject Device	**Predicate Device**
Intended Use	To grasp, hold, retract, or manipulate soft tissue and organs.	Same
Indications for use	The Magnetic Surgical System is designed to grasp and retract the body and the fundus of the gallbladder in laparoscopic cholecystectomy procedures, the liver in bariatric procedures, and the prostate and periprostatic tissue in prostatectomy procedures to facilitate access and visualization of the surgical site. The device is indicated for use in patients with a BMI range of 20-60 kg/m^2.	The Magnetic Surgical System is designed to grasp and retract the body and the fundus of the gallbladder in laparoscopic cholecystectomy procedures and the liver in bariatric procedures to facilitate access and visualization of the surgical site. The device is indicated for use in patients within a BMI range of 20 to 60 kg/m^2.

The subject and predicate device share identical technological characteristics:

- Both devices are composed of two hand-held instruments: a Magnetic Grasper comprised of a detachable Grasper Tip and a Shaft, and an external Magnetic Controller.
- The principles of operation remain unchanged. For both devices, the Magnetic Grasper is actuated manually using the handle of the Shaft to grasp and release tissue; and the Grasper Tip is controlled manually by the handle or the external Magnetic Controller to retract tissue.
- The design, features and materials remain unchanged. The patient-contacting materials of the Magnetic Grasper meet biocompatibility requirements per applicable sections of ISO 10993-1. The Magnetic Controller is not patient-contacting.

As such, the design, materials and function of the subject Magnetic Surgical System are substantially equivalent to the predicate Magnetic Surgical System.

Performance Data:

There were no technological changes to the subject device, thus no bench, animal, electromagnetic compatibility testing, sterilization testing or biocompatibility testing was required.

Clinical performance data demonstrated the subject device is as safe and effective as the predicate device in grasping and retracting soft tissue and organs in prostatectomy procedures.

Special Controls:

The Magnetic Surgical System is subject to the special controls described in §21 CFR 878.4815. These special controls are stated below. Compliance with these requirements has been met as noted in the italicized text below each requirement.

(1) *In vivo* performance data must demonstrate that the device performs as intended under anticipated conditions of use. Testing must demonstrate the ability of the device to grasp, hold, retract, mobilize or manipulate soft tissue and organs.

Clinical performance data from a prospective clinical study of 30 subjects with five participating surgeons was conducted at Fundacion Arturo Lopez Perez in Santiago, Chile to address this special control.

*As shown in the study summary table below (**Table A**), the device was successfully used for retraction of the prostate and periprostatic tissue in prostatectomy procedures. Results of the clinical study met all safety and effectiveness endpoints, demonstrating that the Magnetic Surgical System can be used in robotic-assisted laparoscopic prostatectomy surgery in a safe and effective manner. Investigators reported that adequate retraction was achieved since it was not necessary to replace the MSS with another instrument to retract the prostate during the procedure. There were no cases of severe or serious adverse events related to the device. The reported clinical performance data from the prospective study demonstrated that the device performed as intended in prostatectomy procedures.*

Table A. Summary of Clinical Study

Study Name/Description	Prospective Clinical Study of the Levita Magnetic Surgical System Used for Prostatectomy Surgery
Objective/Type of Study	Prospective, multi-investigator, single-arm, open label study designed to evaluate the safety and effectiveness of the Levita Magnetic Surgical System in patients undergoing prostatectomy surgery
Number of sites/Number of investigators/ Number of subjects/Follow-up time points	1 site; 5 investigators; 30 subjects; follow-up at hospital discharge, 7- and 30-days post-procedure
Inclusion/Exclusion Criteria	• Inclusion criteria included: subject is scheduled to undergo elective prostatectomy surgery • Exclusion criteria included: significant comorbidities (i.e., cardiovascular, neuromuscular, chronic obstructive pulmonary disease, and urological disease (renal failure)), impaired coagulation, subjects with pacemakers, defibrillators, or other electromedical implants, subjects with an anatomical abnormality noted after initiation of index procedure that would prevent device
Procedure	Use of the subject device during robotic-assisted prostatectomy procedures
Study Endpoints	• Ability to adequately retract the prostate to achieve an effective exposure of the target tissue. Adequate retraction was deemed to be achieved if it is not necessary to replace the Levita Magnetic Surgical System with another instrument to retract the prostate during the procedure. • All adverse events were captured and reported. Adverse events were further summarized by relatedness to the device and/or procedure, seriousness and level of severity.
Patient Demographics	Age, mean: 65 Hispanic or Latino: 30 BMI, mean (range): 28.2 kg/m^2 (21.1-36.9 kg/m^2)

Summary of Results	Safety: No cases of severe or serious adverse events and no device-related adverse events. Effectiveness: The MSS was able to adequately retract the prostate to achieve an effective exposure of target tissue. It was not necessary to replace the MSS with another instrument to retract the prostate during the procedure. Procedure Times: Mean overall procedure time was 3 hours 23 minutes.
Summary of Adverse Events	Eleven (11) events were reported throughout the course of the study and adjudicated as adverse events. All eleven events resolved with no clinical sequelae and were categorized as not related to the subject device. No severe or serious adverse events were reported.

(2) Non-clinical performance data must demonstrate that the system performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(a) Magnetic field strength testing characterization to identify the distances from the magnet that are safe for patients and users with ferromagnetic implants, devices or objects.

(b) Ability of the internal surgical instrument(s) to be coupled, de-coupled, and recoupled with the external magnet over the external magnet use life.

The modifications that are the subject of this submission do not change the magnetic field strength or coupling of the internal surgical instrument with the external magnet. Therefore, previously conducted nonclinical performance testing that demonstrated that the device performs as intended under the anticipated conditions of use applies here.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

The modifications that are the subject of this submission do not change any aspect of the device. Therefore, previously conducted testing that demonstrated that the device is biocompatible applies here.

(4) Performance data must demonstrate the sterility of the device components that are patient-contacting.

The modifications that are the subject of this submission do not change any aspect of the device. Therefore, previously conducted testing that demonstrated the sterility of the device applies here.

(5) Methods and instructions for reprocessing reusable components must be validated.

The modifications that are the subject of this submission do not change any aspect of the device. Therefore, previously conducted testing that validated the methods and instructions for reprocessing reusable components applies here.

(6) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components and device functionality over the labeled shelf life.

The modifications that are the subject of this submission do not change any aspect of the device. Therefore, previously conducted testing that validated the shelf life of the device applies here.

(7) Training must be developed and validated by human factors testing and analysis to ensure users can follow the instructions for use to allow safe use of the device.

A training program for use of the Magnetic Surgical System as indicated was developed, and a usability study validating the training program was completed to comply with this special control.

(8) Labeling must include:

(a) Magnetic field safe zones.
(b) Instructions for proper device use.
(c) A screening checklist to ensure that all patients and operating staff are screened from bringing ferromagnetic implants, devices or objects near the external magnet.
(d) Reprocessing instructions for any reusable components.
(e) Shelf life.
(f) Use life.

The labeling complies with the special controls stated above.

Conclusion:

The Magnetic Surgical System has the same intended use as the predicate device as demonstrated by data from a prospective clinical study to support the safety and effectiveness for the new indication compared to the predicate device. In addition, it has the same technological characteristics. Therefore, the Magnetic Surgical System is substantially equivalent to the cleared predicate device.