September 19, 2018

Levita Magnetics International Corp.
% Cindy Domecus
Principal, Domecus Consulting Services LLC
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K180894
Trade/Device Name: Levita Magnetic Surgical System
Regulation Number: 21 CFR 878.4815
Regulation Name: Magnetic Surgical Instrument System
Regulatory Class: Class II
Product Code: PNL
Dated: August 6, 2018
Received: August 7, 2018

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/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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*

K180894

Device Name

Magnetic Surgical System

Indications for Use *(Describe)*

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 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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.
1430 S. Amphlett Blvd, Suite 240
San Mateo, CA 94402
Phone: 650-241-0320
Fax: 650-241-1825

Submission Correspondent:
Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
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
Device Type:	Magnetic Surgical Instrument System
Device Class:	II
Product Code:	PNL

Predicate Device:

Levita Magnetic Surgical System, DEN150007 and K171429

Date Prepared:

September 18, 2018

Device Description:

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

The Magnetic Grasper Device (sterile, single use), comprised of a distal Detachable Grasper attached to a Delivery/Retrieval shaft with Handle, is actuated via its pistol-grip Handle with two distinct scissor-type motions to open and close the Detachable Grasper jaws. Once the Magnetic Grasper Device is inserted

through a compatible ≥ 10 mm laparoscopic port and the Detachable Grasper is attached to the desired tissue, the Detachable Grasper can be detached from the Delivery/Retrieval Shaft and controlled externally using the Magnetic Controller. Traction of the tissue is maintained through the magnetic field attraction between the Detachable Grasper 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 Detachable Grasper. Once the Detachable Grasper is attached to the desired tissue and detached from the Delivery/Retrieval Shaft, the Magnetic Controller is placed external to the body to magnetically attract the Detachable Grasper to manipulate the target tissue. Adjusting the distance between the Magnetic Controller and the Detachable Grasper 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 and the liver in bariatric 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 as magnetic surgical instrument systems used to grasp, hold, retract, or manipulate soft tissue and organs. The subject device differs from the predicate device by only a modification to the Indications for Use and the associated changes to the labeling. The technological characteristics otherwise remain the same. 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, as demonstrated by clinical testing
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 and the liver in bariatric procedures to facilitate access and visualization of the surgical site. The	The Magnetic Surgical System is designed to grasp and retract the body and the fundus of the gallbladder in laparoscopic cholecystectomy procedures to facilitate access and visualization of the surgical site. The device is

	device is indicated for use in patients with a BMI range of 20-60 kg/m^2.	indicated for use in patients within a BMI range of 20 to 34 kg/m^2.

The subject and predicate device share identical technological elements:

- The device description remains unchanged. Both devices are composed of two hand-held instruments: a Magnetic Grasper Device comprised of a Detachable Grasper and a Delivery/Retrieval Shaft and an external Magnetic Controller.
- The principles of operation remain unchanged. For both devices, the Magnetic Grasper Device is actuated manually using the handle of the Delivery/Retrieval Shaft to grasp and release tissue; and the Detachable Grasper 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 Device 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, 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 for liver retraction during laparoscopic bariatric procedures in patients with BMI range of 20-60 kg/m^2.

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 two separate studies totaling 103 subjects was provided to address this special control. A retrospective clinical study of 73 subjects with ten participating surgeons was conducted at the Duke Center for Metabolic and Weight Loss Surgery, and a

prospective clinical study of 30 subjects with three participating surgeons was conducted at Hospital La Florida in Santiago, Chile.

As shown in the two study summary tables below (Table A and Table B), the device was successfully used for retraction of the liver using a reduced port technique in all 103 total subjects evaluated. Results of both clinical studies demonstrated that the device could be used to grasp and retract the liver in laparoscopic bariatric procedures in a safe and effective manner. There were no cases of severe or serious adverse events related to the device and no cases of device failure or malfunctions reported in either study. In both studies, the device was able to adequately grasp and retract the liver to achieve an effective exposure of the target tissue and perform the bariatric procedure. Also, in both studies, overall procedure times were similar to published averages, and it was not necessary to use another instrument to retract the liver during the procedure. All 103 cases were performed using a reduced port technique, avoiding an incision for a liver retractor.

The reported clinical performance data from the retrospective study and prospective study demonstrate that the device performs as intended to grasp, hold, and retract the liver under anticipated conditions of use.

Table A. Summary of Prospective Study

Study Name/Description	Prospective Study of Liver Mobilization with the Levita Magnetic Surgical System
Objective/Type of Study	A prospective, single arm, open label study to evaluate the safety and effectiveness of the Levita Magnetic Surgical System in patients undergoing bariatric procedures
Number of sites/Number of investigators/ Number of patients/Follow-up time points	1 site, 3 investigators, 30 patients treated, follow-up at hospital discharge, 7- and 30-days post-procedure
Inclusion/Exclusion Criteria	• Inclusion criteria included: subject is scheduled to undergo elective bariatric procedure such as Sleeve Gastrectomy, Gastric By Pass, Duodenal Switch or Bariatric Revisional Surgery • Exclusion criteria included: signs of hepatic abnormality (e.g.: cirrhosis, liver failure, increase in liver enzymes, etc.), impaired coagulation, American Society of Anesthesiologists (ASA) score of III or IV, subjects with pacemakers, defibrillators, or other electromedical implants
Procedure	Use of the subject device during laparoscopic bariatric procedures using reduced port technique, avoiding an incision for a liver retractor
Study Endpoints	• Ability to adequately retract the liver to achieve an effective exposure of the target tissue. Adequate mobilization was not achieved if it was necessary to use another instrument to retract the liver 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	Female: 28 (93%) Age, mean: 43 BMI, mean (range): 41.5 kg/m^2 (33.6-58.2 kg/m^2)
Summary of Results	Safety: No cases of severe or serious adverse events related to the device. No cases of device failure or malfunctions. Effectiveness: In all cases, the MSS was able to adequately retract the liver to achieve an effective exposure of the target tissue and perform the bariatric procedure. It was not necessary to use another instrument to retract the liver during the procedure. Procedure Times: Mean time to place the grasper on the liver was 1 minute 2 seconds; Mean time to couple the Detachable Grasper with the Magnetic Controller was 1 minute and 10 seconds; Mean overall procedure time was 55 minutes. For sleeve gastrectomy, the average was 44 minutes and for gastric by-pass and revisional surgery, the average was 1 hour 32 minutes.
Summary of Adverse Events	Twelve (12) AEs were categorized as definitely device-related. Six (6) of these were internal mild petechiae noted during the procedure. Internal mild petechiae was noted as resolved based on physical examination at follow up (i.e., normal external abdominal wall appearance and asymptomatic subject). The other six (6) adverse events were minor liver capsule abrasion, without bleeding or clinically relevant concern, observed at the procedure. All minor abrasions were noted as resolved based on asymptomatic subject at follow up. All device-related events were categorized as mild and all resolved with no reports of clinical sequelae.

Table B. Summary of Retrospective Study

Study Name/Description	Magnetic Liver Retraction: An Incision-Less Approach for Less Invasive Bariatric Surgery
Objective/Type of Study	A retrospective single arm study to evaluate the safety and effectiveness of the Levita Magnetic Surgical System in patients undergoing bariatric procedures
Number of sites/Number of investigators/ Number of patients/Follow-up time points	1 site, 10 investigators, 73 patients treated, mean follow-up: 2.2 months post-procedure (range: 0.5-9 months)

Inclusion/Exclusion Criteria	• Inclusion criteria included: Consecutive bariatric procedure patients between October 2016 and August 2017 • Exclusion criteria: None reported
Procedure	Use of the subject device during laparoscopic bariatric procedures using reduced port technique, avoiding an incision for a liver retractor
Study Endpoints	The study manuscript described results on the following parameters: • Successful completion of laparoscopic bariatric surgery using the Magnetic Surgical System • Mean operative times • Intraoperative complications, morbidity and mortality at follow-up were captured and reported. Complications were further summarized by relatedness to the device.
Patient Demographics	Female: 59 (81%) Age, mean: 43 BMI, mean (range): 43.6 kg/m^2 (18.3-67.7 kg/m^2)
Summary of Results	Safety: No cases of severe or serious adverse events related to the device were reported. Effectiveness: In all cases, the MSS was able to adequately retract the liver to achieve an effective exposure of the target tissue and perform the bariatric procedure. It was not necessary to use another instrument to retract the liver during the procedure. Procedure Times: The average operative times were: laparoscopic sleeve gastrectomy, 68 min.; laparoscopic Roux-en-Y gastric bypass, 134 min.; laparoscopic duodenal switch, 240 min.; laparoscopic adjustable gastric band, 75 min., revision, 167 min.
Summary of Adverse Events	Two patients experienced minor thirty-day morbidities (nausea/emesis and transient ischemic attack), neither of which were attributed to the device and did not require further interventions. There were no thirty-day mortalities. None of the patients experienced any liver-related complications and no skin compression damage was observed at the site of placement of the external magnet.

(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 in the predicate indication to grasp and retract the gallbladder in laparoscopic cholecystectomy procedures was developed and underwent a human factors validation in support of the original marketing authorization for the device. An analysis was performed to determine if the revision to the Indications for Use to also include use of the device to grasp and retract the liver in bariatric procedures and in patients with a higher BMI required either a revision to the training program and/or a new human factors validation of the training program. The training program was updated to reflect the revised Indications for Use and accompanying labeling that is specific to the liver; however, these changes do not require a new human factors validation of the training for the following reasons: 1) the device design is unchanged, 2) the evaluation of Known Use Problems identified

no new use problems for the revised indication, 3) analysis of Hazards and Risks Associated with Use of the Device determined the use-related hazards and mitigations are unchanged, and 4) the Critical Tasks and Critical Task Errors are the same for grasping and retracting the gallbladder and the liver. This assessment is supported by the clinical performance data from the two clinical studies (involving a total of 13 surgeons using the device in a total of 103 subjects) submitted in support of the revised Indications for Use. The validated user training program updated for the additional indication was used to train the investigators participating in the prospective study. The study results met all predefined safety and effectiveness endpoints and demonstrated that the device can be used to grasp and retract the liver in laparoscopic bariatric procedures in a safe and effective manner. Therefore, previously conducted human factors testing which validated that users can follow the instructions to allow safe use of the device applies to the revised Indications for Use and physician training is still recommended as a risk control measure.

(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 clinical studies to support the safety and effectiveness for the new indications 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.