DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 6, 2017

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

Re: K171429
Trade/Device Name: Magnetic Surgical System
Regulation Number: 21 CFR 21 CFR §878.4815
Regulation Name: Magnetic surgical instrument system
Regulatory Class: Class II
Product Code: PNL
Dated: May 11, 2017
Received: May 15, 2017

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171429

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 to facilitate access and visualization of the surgical site. The device is indicated for use in patients within a BMI range of 20 to 34 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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Special 510(k) Summary (21 CFR § 807.92(c))

I: SUBMITTER INFORMATION

- **Submitter:** Levita Magnetics International Corporation
  1730 S Amphlett Blvd, Suite 240
  San Mateo, CA 94402

- **Contact:** Cindy Domecus, R.A.C. (US & EU)
  Principal, Domecus Consulting Services LLC
  DomecusConsulting@comcast.net
  (650) 343-4813

Date Summary Prepared: 04 June 17

II: SUBJECT DEVICE INFORMATION

Device Trade Name: Magnetic Surgical System (Model No.: FGA1051 and FGA1055)
Common Name: Magnetic Surgical System
Classification Name: Magnetic Surgical Instrument System
(21 CFR §878.4815)
Product Code: PNL
Regulatory Classification: Class II

III: PREDICATE DEVICE INFORMATION

Predicate Device: Magnetic Surgical System (DEN150007)

No reference devices were used in this submission.

IV: DEVICE DESCRIPTION

The Magnetic Surgical System is composed of two hand-held instruments: a Magnetic Grasper Device and an external Magnetic Controller. The Magnetic Grasper Device is comprised of two main components: a Detachable Grasper and a Delivery/Retrieval Shaft. Once the Magnetic Grasper Device is inserted and the 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 Grasper and the Magnetic Controller. The Magnetic Grasper Device is compatible with a ≥ 10 mm laparoscopic port. The Magnetic Controller 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 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/manipulation.

V: 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 to facilitate access and visualization of the surgical site. The device is indicated for use in patients within a BMI range of 20 to 34 kg/m^2.

VI: MODIFICATIONS OF SUBJECT DEVICE

No modifications are being made to the subject device or the cleared indications for use. This 510(k) is being submitted for a labeling change to the Instructions for Use. Specifically, the subject change is for an update regarding the use life statement.

VII:. DESIGN CONTROL ACTIVITIES

A review of the Risk Analysis previously conducted in support of DEN 150007 was performed to assess the impact of the proposed modification to the use life statement. This assessment included a review of the hazard analysis, design FMEA and use FMEA. The review confirmed that the proposed change does not adversely change the risk profile of the device. The anticipated hazards and harms remain adequately addressed by the controls already in place and no additional testing was deemed necessary.

VIII: 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.

The modifications that are the subject of this submission do not change the performance characteristics of the device. Therefore, previously conducted in vivo performance testing that demonstrated that the device performs as intended under the anticipated conditions of use applies here.

(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 performance characteristics of the device. 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.

The modifications that are the subject of this submission do not change any aspect of the device. Therefore, previously conducted human factors testing which validated that users can follow the instructions to allow safe use of the device applies here.

(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.

IX: CONCLUSION

Modification of the use life statement has no impact on the safety and effectiveness of the Magnetic Surgical System. As such, the modified device is substantially equivalent to the predicate device.