June 7, 2025

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

Re: K250746
Trade/Device Name: Magnetic Surgical System
Regulation Number: 21 CFR 878.4815
Regulation Name: Magnetic Surgical Instrument System
Regulatory Class: Class II
Product Code: PNL
Dated: May 14, 2025
Received: May 14, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.06.07 22:43:16 -04'00'

James Jang, Ph.D.
Acting 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250746

Device Name

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; the pillar of the diaphragm and peripillar tissue in bariatric or hiatal hernia procedures; the prostate and periprostatic tissue in prostatectomy procedures; and the colon, rectum, and pericolorectal tissue in colorectal 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.

The Grasper Tip, 12.5 is designed to grasp and retract the pillar of the diaphragm and peripillar tissue in bariatric or hiatal hernia 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.

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510(k) #: K250746

510(k) Summary

Prepared on: 2025-05-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Levita Magnetics International Corp.
Applicant Address	453 Ravendale Drive Mountain View CA 94063 United States
Applicant Contact Telephone	408-595-6240
Applicant Contact	Ms. Donielle Baudin
Applicant Contact Email	dbaudin@levita.com
Correspondent Name	Domecus Consulting Services
Correspondent Address	1171 Barroilhet Drive Hillsborough CA 94010 United States
Correspondent Contact Telephone	650-773-3445
Correspondent Contact	Ms. Cindy Domecus
Correspondent Contact Email	cindy@domecusconsulting.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Magnetic Surgical System
Common Name	Magnetic surgical instrument system
Classification Name	Magnetic Surgical System
Regulation Number	878.4815
Product Code(s)	PNL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K191762	Levita Magnetic Surgical System	PNL

Device Description Summary

21 CFR 807.92(a)(4)

The Magnetic Surgical System comprises two hand-held instruments, the Magnetic Grasper and the external Magnetic Controller. The Magnetic Grasper, disposable and provided sterile for single use, comprises two main components: a detachable Grasper Tip (6.5cm overall length) and a Shaft with Handle. An optional 12.5cm length Grasper Tip (also single use, disposable, and provided sterile) may be used as a replacement for the 6.5cm Grasper Tip and can be used interchangeably with the Shaft.

The Magnetic Grasper is actuated via its pistol-grip handle with two distinct scissor-type motions to open and close the Grasper Tip jaws. Once the Magnetic Grasper is inserted through a compatible ≥ 10 mm laparoscopic port to the surgical site 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 is a non-sterile, reusable unit with handles that is held external to the body and emits a magnetic field that attracts the detachable 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.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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; the pillar of the diaphragm and peripillar tissue in bariatric or hiatal hernia procedures; the prostate and periprostatic tissue in prostatectomy procedures; and the colon, rectum, and pericolorectal tissue in colorectal 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.

The Grasper Tip, 12.5 is designed to grasp and retract the pillar of the diaphragm and peripillar tissue in bariatric or hiatal hernia 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Compared to the K191762 predicate device, the Indications for Use statement has been modified to add grasping and retracting of the pillar of the diaphragm and peripillar tissue in bariatric and hiatal hernia procedures. The difference does not constitute a new intended use because the labeling modification does not affect the intended use of the predicate device, which is to grasp, hold, retract, mobilize or manipulate soft tissue and organs, and does not raise different questions of safety and effectiveness as compared to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device comprises the modified Magnetic Grasper; the Magnetic Controller, which is unchanged compared to the predicate device; and the Grasper Tip, 12.5 line extension to the Magnetic Grasper.

The modified Magnetic Grasper includes minor changes to materials and manufacturing processes and is labeled with a 12-month shelf life, as compared to 6-months for the predicate device.

The line extension is a longer, detachable Grasper Tip (12.5 cm) that may be used with the Shaft of the Magnetic Grasper in lieu of the 6.5 cm detachable Grasper Tip included with the Magnetic Grasper.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Substantial equivalence is supported by the results of mechanical performance testing of the modified Magnetic Grasper and the Grasper Tip, 12.5 line extension; human factors assessment in accordance with IEC 62366-1 (Recognition Number 5-129), which concluded no additional human factors validation testing is required for the changes; biocompatibility testing of the Grasper Tip, 12.5 line extension in accordance with ISO 10993-1 (2-258); sterilization adoption testing for the line extension per AAMI TIR35, ISO 11137-1 (14-528), and ISO 11137-2 (14-580); real-time shelf-life testing of the modified Magnetic Grasper; and packaging testing for the line extension in accordance with FDA recognized consensus standards, including ASTM F2096 (14-359) and ASTM F88 (14-596). The subject device passed all tests and met all acceptance criteria.

The risk profile of the subject device was assessed per risk management activities in accordance with FDA-recognized consensus standard ISO 14971: 2019 (Recognition Number 5-125) and Levita Magnetics risk management standard procedures to evaluate potential risks associated with the proposed modification to the Indications for Use. No new or different risks were identified.

These results demonstrate that for the entirety of the labeled shelf-life of 12 months, all design requirements and performance specifications have been met and the design conforms to user needs and meets the intended use. These results demonstrate that any technological differences compared to the predicate device do not result in different questions of safety and effectiveness and support substantial equivalence of the subject device to the predicate device.

A prospective, single-arm, open label clinical study was conducted to evaluate the performance and risks related to the subject labeling modification. The clinical study was designed to assess the safety and performance of the Levita Magnetics MSS, including the the Grasper 12.5 line extension for grasping the liver and/or tissue surrounding the crus, or pillar, of the diaphragm in patients undergoing bariatric and/or hiatal hernia procedures.

Thirty (30) subjects were enrolled and underwent bariatric and/or hiatal hernia surgery with the MSS and Levita Magnetics Surgeon Controlled Arm (K223673) by five (5) surgeons at three (3) sites in Santiago, Chile. Subjects were followed for thirty (30) days post-procedure, with follow-up visits at hospital discharge, seven (7), and thirty (30) days post-procedure. The MSS with Grasper Tip, 12.5 attached to the Magnetic Grasper shaft was used as a retractor of the crus of the diaphragm, and the various tissues in the vicinity of the diaphragm. The study results met all predefined safety and performance endpoints and demonstrated that the device can be used in bariatric and/or hiatal hernia procedures in a safe and effective manner.

The safety results met the criteria outlined for the primary safety endpoint for this study; there were no severe or serious adverse events related to the device. The device performance results met the predefined performance endpoints. Specifically, in all 30 cases, the MSS was able to grasp the pillar of the diaphragm or peripillar tissue to adequately mobilize the liver, achieving an effective exposure of the target tissue. It was not necessary to use another liver retractor during any procedures. No procedures required conversion to an open surgical approach. There were no reported device malfunctions that led to conversions to open surgery or use of another liver retractor.

There were no unanticipated adverse events related to the device and no serious or severe adverse events related to the device.

The surgical techniques used in the study conducted in Chile are well-established and are the same techniques routinely used in the United States. The pivotal clinical study provided in support of marketing authorization of the MSS under DEN150007 and the three prospective studies provided in support of expansion of the indication for use in bariatric procedures per K180894, in prostatectomy procedures per K190006, and in colorectal procedures per K191762 were also conducted in Chile.

The clinical performance data demonstrates that the device is safe and effective for its intended use, that the expanded indication does not raise different questions of safety or effectiveness, and supports substantial equivalence to the predicate device.

The results of clinical testing, bench performance testing, packaging integrity testing, sterility testing, shelf-life testing,and biocompatibility testing of the subject device passed all the pre-determined acceptance criteria and demonstrate that the subject device performs as intended under the proposed Indications for Use. Together with the results of risk assessment, they show the subject device does not raise different questions of safety and effectiveness compared to the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.