



September 26, 2025

Levita Magnetics International Corp
% Cindy Domecus
Principal
Domecus Consulting Services
1171 Barroiht Drive
Hillsborough, California 94070

Re: K252435

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: August 1, 2025
Received: August 1, 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,

Colin K.
Chen -S

Digitally signed by
Colin K. Chen -S
Date: 2025.09.26
13:24:49 -04'00'

Colin Kejing Chen, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252435

Please provide the device trade name(s).

Magnetic Surgical System

Please provide your Indications for Use below.

The Magnetic Surgical System is indicated for use in patients within a BMI range of 20 to 60 kg/m² and designed to grasp and retract soft tissues and organs to facilitate access and visualization of the surgical site for the following:

- The body and fundus of the gallbladder in laparoscopic cholecystectomy procedures
- The liver in bariatric procedures
- The prostate and periprostatic tissue in prostatectomy procedures
- The colon, rectum, and pericorectal tissue in colorectal procedures

The Grasper Tip 12.5 is indicated for use in patients within a BMI range of 20 to 60 kg/m² and designed to grasp and retract soft tissues and organs to facilitate access and visualization of the surgical site for the following

- The pillar of the diaphragm and peripillar tissue in bariatric or hiatal hernia procedures

Pediatric use:

The Magnetic Surgical System is indicated for use in adolescents (12-21) within a BMI range of 20 to 34 kg/m² and designed to grasp and retract soft tissues and organs to facilitate access and visualization of the surgical site for the following:

- The body and fundus of the gallbladder in laparoscopic cholecystectomy procedures

Please select the types of uses (select one or both, as applicable).

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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
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Correspondent Contact	Ms. Cindy Domecus
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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
K250746	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 Magnetic Surgical System is indicated for use in patients within a BMI range of 20 to 60 kg/m² and designed to grasp and retract soft tissues and organs to facilitate access and visualization of the surgical site for the following:

- The body and fundus of the gallbladder in laparoscopic cholecystectomy procedures
- The liver in bariatric procedures
- The prostate and periprostatic tissue in prostatectomy procedures
- The colon, rectum, and pericorectal tissue in colorectal procedures

The Grasper Tip 12.5 is indicated for use in patients within a BMI range of 20 to 60 kg/m² and designed to grasp and retract soft tissues and organs to facilitate access and visualization of the surgical site for the following

- The pillar of the diaphragm and peripillar tissue in bariatric or hiatal hernia procedures

Pediatric use:

The Magnetic Surgical System is indicated for use in adolescents (12-21) within a BMI range of 20 to 34 kg/m² and designed to grasp and retract soft tissues and organs to facilitate access and visualization of the surgical site for the following:

- The body and fundus of the gallbladder in laparoscopic cholecystectomy procedures

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

Compared to the K250746 predicate device, the only difference is an expanded patient population indicated for laparoscopic cholecystectomy 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 Magnetic Grasper; the Magnetic Controller, and the Grasper Tip, 12.5. The subject device has the same technological characteristics as the predicate device because it is identical to the predicate device, with exception of the labeling.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The subject device is identical to the predicate device, with exception of expansion of the patient population for use in laparoscopic cholecystectomy to include adolescent patients (aged 12-21 years) with a range of BMI of 20 to 34 kg/m². The information pertaining to nonclinical tests previously provided is incorporated by reference to K250746, specifically, the "Performance Testing" section of the eSTAR file and Attachments 15-21 provided in its "Bench Testing" section.

The risk profile of the subject device for the proposed adolescent patient population with BMI of 20 to 34 kg/m² 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 and no additional nonclinical testing is required.

These results demonstrate that as demonstrated by the above referenced testing, all design requirements and performance specifications have been met and the design conforms to user needs and meets the intended use. These results support substantial

equivalence of the subject device to the predicate device.

As described in Attachment 9: Justification for Extrapolation, the results of the CR001 clinical study that successfully supported the DEN150007 de novo decision for use in laparoscopic cholecystectomy procedures within the adult patient population may be leveraged to demonstrate that the subject device performs as intended under the Indications for Use proposed for the adolescent patient population. The review of peer-reviewed clinical publications summarized in Attachment 9 determined the existing data from the CR001 clinical study is relevant to an adolescent indication; the course of gallbladder disease indicated for laparoscopic cholecystectomy and the effects of the device are sufficiently similar in adult and adolescent populations; and the CR001 data constitutes valid scientific evidence.

The results of CR001 demonstrated that the MSS met primary safety and performance endpoints.

The results of the referenced testing of the predicate device (i.e. bench testing, packaging integrity testing, sterility testing, shelf-life testing, biocompatibility testing, and bench performance testing), as well as referenced clinical testing per DEN150007, all met 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.