



Food and Drug Administration
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June 13, 2016

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

Re: DEN150007
Levita Magnetic Surgical System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 878.4815
Regulation Name: Magnetic Surgical Instrument System
Regulatory Classification: Class II
Product Code: PNL
Dated: February 9, 2015
Received: February 10, 2015

Dear Ms. Domecus:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Levita Magnetic Surgical System, a prescription device under 21 CFR Part 801.109 that is indicated “*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.*” FDA concludes that this device should be classified into class II. This order, therefore, classifies the Levita Magnetic Surgical System, and substantially equivalent devices of this generic type, into class II under the generic name, Magnetic Surgical Instrument System.

FDA identifies this generic type of device as:

Magnetic Surgical Instrument System. A magnetic surgical instrument system is a prescription device used in laparoscopic surgical procedures consisting of several components, such as surgical instruments, and a magnetic controller. The magnetic controller is provided separately from the surgical instrument and is used outside the patient. The external magnetic controller is magnetically coupled with the internal surgical instrument(s) at the surgical site to grasp, hold, retract, mobilize or manipulate soft tissue and organs.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE

determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On February 10, 2015, FDA received your *de novo* requesting classification of the Levita Magnetic Surgical System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Levita Magnetic Surgical System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Levita Magnetic Surgical System indicated “*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.*” can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Tissue Damage	<ul style="list-style-type: none"> • <i>In vivo</i> Performance Testing • Human Factors Testing and Analysis • Training • Labeling
Need for Extended or Additional Surgery: <ul style="list-style-type: none"> • Inability to couple the external magnet with the internal surgical instrument • Inability to retrieve or maneuver device • Inability to visualize critical anatomical structures 	<ul style="list-style-type: none"> • <i>In vivo</i> Performance Testing • Non-clinical Performance Testing • Human Factors Testing and Analysis • Training • Labeling
Abdominal Wall Injury	<ul style="list-style-type: none"> • <i>In vivo</i> Performance Testing • Human Factors Testing and Analysis • Labeling
Electromagnetic Field Incompatibility or Interference (including ferromagnetic implants in users and patients, electrosurgical devices, etc.)	<ul style="list-style-type: none"> • Non-clinical Performance Testing • Human Factors Testing and Analysis • Training • Labeling
Adverse Tissue Reaction	<ul style="list-style-type: none"> • Biocompatibility Evaluation

Identified Risk	Mitigation Measures
Infection	<ul style="list-style-type: none"> • Sterilization Validation • Reprocessing Validation • Shelf Life Validation • Labeling

In combination with the general controls of the FD&C Act, Magnetic surgical instrument system are subject to the following special controls:

- (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.
- (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 re-coupled with the external magnet over the external magnet use life.
- (3) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (4) Performance data must demonstrate the sterility of the device components that are patient-contacting.
- (5) Methods and instructions for reprocessing reusable components must be validated.
- (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.
- (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.
- (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.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Magnetic Surgical Instrument System they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Dr. Binita Ashar at 301-796-6385.

Sincerely,

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health