DE NOVO CLASSIFICATION REQUEST FOR LEVITA MAGNETIC SURGICAL SYSTEM

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 878.4815

CLASSIFICATION: II

PRODUCT CODE: PNL

BACKGROUND

DEVICE NAME: LEVITA MAGNETIC SURGICAL SYSTEM

SUBMISSION NUMBER: DEN150007

DATE OF DE NOVO: FEBRUARY 10, 2015

CONTACT: LEVITA MAGNETICS INTERNATIONAL CORP.
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REQUESTER'S RECOMMENDED CLASSIFICATION: II

INDICATIONS FOR USE

The Levita 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.

LIMITATIONS

The sale, distribution, and use of the Levita Magnetic Surgical System are restricted to prescription use in accordance with 21 CFR 801.109.

Limitations on device use are also achieved through the following statements included in the instructions for use:

Contraindications:

- Do not use on patients or near anyone with pacemakers, defibrillators, or other electromedical implants.
- Do not use on patients or near anyone with ferromagnetic implants.

Warnings and Precautions:

Failure to adhere to the instructions below may result in patient or user injury and/or damage to the device.

- Do not use on patients or near anyone who does not pass the Magnetic Surgery Screening Checklist. A screening checklist is provided by Levita Magnetics for this purpose.
- Do not use the Magnetic Controller to attempt to retrieve a lost Detachable Grasper. Doing so could result in significant patient harm, including significant damage to tissue and/or vasculature.
- The Magnetic Controller contains a strong magnet. Safe working zones have been defined for the Magnetic Controller. Adhere to the safe zones described in the following tables, and maintain a safe working distance. Failure to adhere to the safety zones may result in patient and/or user injury.

Safe Zones for Magnetic Controller *Outside of Carrying Case* Category	**Safe Working Distance. Do not position closer than distance specified.**
Personnel/patients with cardiac pacemakers, or medical implants	50 cm (20 inches)
Equipment with cathode-ray tubes (i.e. CRT monitors)	50 cm (20 inches)
Equipment with magnetic data storage	50 cm (20 inches)
Small ferromagnetic objects	25 cm (10 inches)
General electrical equipment	25 cm (10 inches)

Safe Zones for Magnetic Controller *Inside of Carrying Case* Category	**Safe Working Distance. Do not position closer than distance specified.**
Personnel/patients with cardiac pacemakers, or medical implants	50 cm (20 inches)
Equipment with cathode-ray tubes (i.e. CRT monitors)	50 cm (20 inches)
Equipment with magnetic data storage	20 cm (8 inches)
Small ferromagnetic objects	5 cm (2 inches)
General electrical equipment	5 cm (2 inches)

- Place the manufacturer-supplied safety signage on all entry doors of the operating room.
- The safety and effectiveness of the Magnetic Surgical System for use in patients with BMI <20 or >34 has not been established.
- Assess the gallbladder and do not use the Magnetic Surgical System if adhesions, stones, or fibrosis interfere with exposure of the critical view of safety or

definition of the components of the hepatocystic triangle.

- When the Detachable Grasper is detached from the gallbladder, reestablishing attachment requires a greater number of steps and may be more time consuming than with a shafted (i.e., traditional) grasper.
- Placement of an additional trocar port may be required if exposure is inadequate and/or additional treatment is needed after complete removal of the gallbladder from the hepatic bed.
- The Magnetic Grasper Device should be used to grasp only the fundus or the body of the gallbladder.
- The Magnetic Grasper Device is for single use only. Do not resterilize or reuse.
- Do not use multiple Magnetic Controllers simultaneously.
- Inability to adequately grasp, retract and /or mobilize target tissue using the Magnetic Surgical System during the procedure may require the use of an additional trocar to complete the surgery.
- Always store the Magnetic Controller in the manufacturer-supplied carrying case.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Levita Magnetic Surgical System is composed of two hand-held instruments, the Magnetic Grasper Device and external Magnetic Controller, which are intended to facilitate tissue grasping, retraction and mobilization during laparoscopic cholecystectomy procedures.

1. Magnetic Grasper Device (sterile, single use) – is actuated via its pistol-grip handle with two distinct scissor-type motions to open and close the Detachable Grasper jaws as shown in Figure 1. At the distal end is the Detachable Grasper, which is attached to the Delivery/Retrieval Shaft of the full Magnetic Grasper Device. This device requires a ≥10mm access port to introduce the device into the abdominal cavity. The Detachable Grasper is then coupled (held in place within the abdomen) by the external Magnetic Controller. If the surgeon wishes to use a single 10-12 mm port at the umbilicus such as a Hasson port and that is the port shared by the optic, applying and adjusting the Detachable Grasper may require repetitive placement of the optic in an alternative port. The Detachable Grasper is shown in Figure 2.

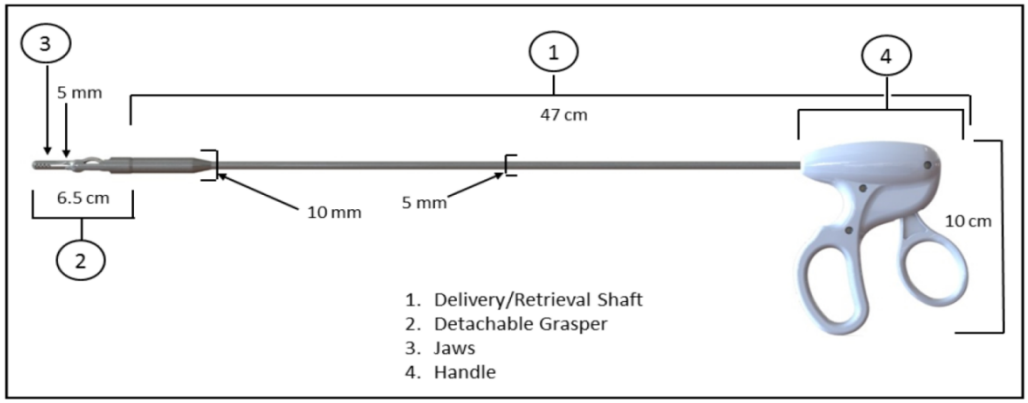

Figure 1 – Magnetic Grasper Device

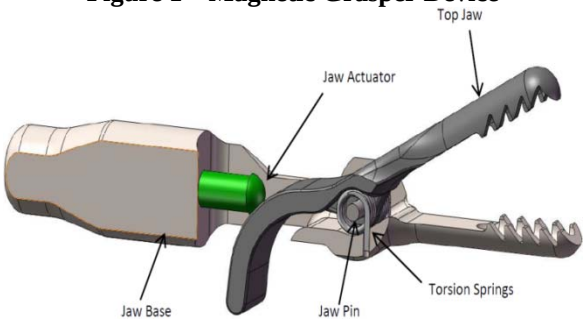

Figure 2 – Detachable Grasper

2. An External Magnetic Controller (non-sterile, reusable) - 3-inch diameter by 2-inch thick b(4) disk magnet, shown in Figure 3. This component holds the Detachable Grasper (magnetically) and is placed on the external abdomen wall.
   - Surface field strength of b(4) CCI/ Gauss within an encasement with integrated handles. Static field and does not induce current flow.
   - Mounting stem for optionally attaching it to a commercially available surgical support arm.
   - Comprised of ferromagnetic material – If the External Magnetic Controller is moved within a short distance of the interior abdominal wall, it can act on the internally placed Detachable Grasper, pulling it toward the abdominal wall.
   - The user varies the distance required to achieve the necessary attraction between the Detachable Grasper and Magnetic Controller during the procedure.

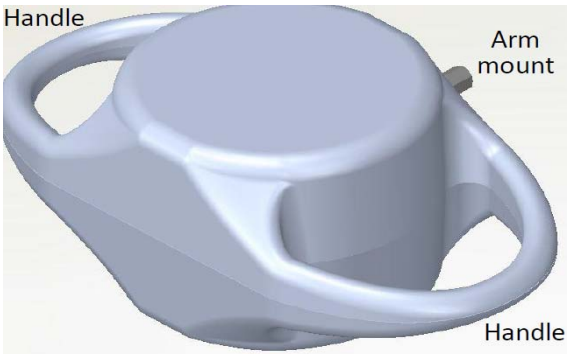

Figure 3 – External Magnetic Controller

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

Biocompatibility testing was not conducted on the Magnetic Controller because it is not patient-contacting. It is a noncritical reusable device because it is placed in a sterile bag or covered with a drape during use and does not have direct contact with the patient's skin.

Biocompatibility testing was conducted on the Magnetic Grasper Device in accordance with the FDA's modified matrix Blue Book Memorandum #G95-1, entitled Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices, Part 1 Evaluation and Testing within a risk management process. The tests were performed on the patient-contacting materials identified in Table 1 below. As seen in Table 2, the tests performed included cytotoxicity, sensitization, and irritation.

Table 1: Patient Contacting Materials

Components	Materials
Torsion Springs	b(4) Stainless Steel
Top Jaw	b(4) Stainless Steel
Jaw Actuator, Jaw Pin, Shaft, Distal Taper, Actuation Rod, Magnet Puller	b(4) Stainless Steel
Jaw Base	b(4 Stainless Steel
Cup Tip, Magnet Stop	b(4 Stainless Steel

Table 2: Biocompatability Tests

Biocompatibility Test	Standard	Acceptance Criteria	Results
Cytotoxicity (MEM Elution)	ISO 10993-5	Test Sample Reactivity ≤ 2	PASS
Sensitization (0.9% NaCl, sesame oil)	ISO 10993-10	Test samples < 1 grade dermal reaction	PASS
Irritation/Intracutaneous Reactivity (0.9% NaCl, sesame oil)	ISO 10993-10	Control extract overall mean score ≤ 1.0	PASS

SHELF LIFE/STERILITY

The detachable grasper component of the Levita Magnetic Surgical System is provided sterile and is single use. The device is sterilized by gamma sterilization process with a dose of 27.5 kGy to 40 kGy, which achieves a sterility assurance level (SAL) of 10^{-6} and is performed in accordance with the following standards:

Table 3: Detachable Grasper Sterilization Testing Standards

Standards	Results
ISO 11737-1:2006 Sterilization of health care products – Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	PASS
ISO 11137-2: 2012 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose	PASS

Standards	Results
AAMI TIR33:2005 Sterilization of health care products-Radiation -Substantiation of a selected sterilization dose - Method b(4)	PASS

The second component, the Magnetic Controller, is a reusable component of the Magnetic Surgical System and is provided non-sterile. It is a noncritical reusable device because it is placed in a sterile bag or covered with a drape during use and does not have direct contact with the patient's skin. The Magnetic Controller is cleaned and then receives intermediate level disinfection prior to reuse on another patient.

Shelf life for the detachable gasper was determined to be 6 months based on accelerated aging, as demonstrated in Table 4 and the design verification tests summarized in Table 8 in the PERFORMANCE TESTING – BENCH section below.

Table 4: Detachable Grasper Shelf Life Testing

Test	Acceptance criteria	Results
Shelf-life visual inspection: outer box damage	No visible damage	PASS
Shelf-life visual inspection: outer box label	Label is legible	PASS
Shelf-life visual inspection: pouch damage	No visible damage	PASS
Shelf-life visual inspection: pouch label	Label is legible	PASS

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

There are no electrical components in the Levita Magnetic Surgical System; therefore electrical safety and compatibility testing are not applicable. However, as a magnetic system, magnetic field strength testing was provided to determine the safe working zones for the Magnetic Controller and to address the risk of magnetic field interference with electromedical equipment and ferromagnetic instruments and implants.

The strength of the static magnetic field was measured at distances of b(4) , and bb(4) (from the face of the magnet b(4) CCI/ , with and without the carrying case. By determining the magnetic field strength at several distances, the safe working zones for use of the device were determined. Safe zones were defined based on the characterization data compared with guidelines established in publications by the American Conference of Industrial Hygienists (ACGIH), the International Commission on Non-ionizing Radiation Protection, and the National Research Council (NRC) regarding occupational safety and laboratory practices and safe general public exposure. The summary of the results can be found in the following tables (Tables 5 and 6):

Table 5: Test Data with External Magnetic Controller In Case

	Measured Magnetic Field Strength
Max. Magnetic flux @b(4) on 3 samples	b(4)
Min. Magnetic flux @ b(4) on 3 samples	b(4)
Average	15.15 G
Standard Deviation	13.85 G
Max. Magnetic flux @ b(4) on 3 samples	b(4)
Min. Magnetic flux @ b(4) on 3 samples	b(4)
Average	4.25 G
Standard Deviation	3.75 G
Max. Magnetic flux @ b(4) on 3 samples	b(4)
Min. Magnetic flux @ b(4) on 3 samples	b(4)
Average	3.45 G
Standard Deviation	0.25 G

Table 6: Test Data with External Magnetic Controller Outside Case

	Measured Magnetic Field Strength
Max. Magnetic flux @ b(4) on 3 samples	b(4)
Min. Magnetic flux @ b(4) on 3 samples	b(4) G
Average	18.25 G
Standard Deviation	2.45 G
Max. Magnetic flux @ b(4) on 3 samples	b(4)
Min. Magnetic flux @ b(4) on 3 samples	b(4)
Average	2.95 G
Standard Deviation	0.55 G
Max. Magnetic flux b(4) cm on 3 samples	b(4)
Min. Magnetic flux b(4) on 3 samples	b(G
Average	1.45 G
Standard Deviation	0.65 G

PERFORMANCE TESTING – BENCH

Testing was performed to verify the device design. Performance criteria were evaluated by conducting mechanical testing intended to show both functional performance and mechanical integrity. The design verification testing included evaluations to address performance characteristics that would be affected by aging. Specifically, the functional verification testing included force testing to be assured of the device ability to perform the desired functions, such as grasping the tissue (Table 7). The sponsor also tested how the forces would be affected after accelerated aging to 6 months (Table 8).

Table 7: Device Design Verification Testing: Functional (T = 0 months)

Test	Acceptance Criteria	Results
Grasper Pull-off force	b(4) CCI/TS	PASS
Grasper Pull-off force when near Magnetic Controller		PASS
Grasper Jaw Pinch Force		PASS
Handle force to open grasper jaws		PASS
Minimum grasper jaw opening		PASS
Handle force to release grasper jaws		PASS
Attraction force to external magnet at a distance of 4 cm		PASS
Lifetime Cycling Performance (all above tests) after simulated use and actuations over lifetime	Same as all above	PASS

Table 8: Device Design Verification Testing: Functional (T = 6 months)

Test	Acceptance Criteria	Results
Grasper Pull-off force	b(4) CCI/TS	PASS
Grasper Pull-off force when near Magnetic Controller		PASS
Grasper Jaw Pinch Force		PASS
Handle force to open grasper jaws		PASS
Minimum grasper jaw opening		PASS
Handle force to release grasper jaws		PASS
Attraction force to external magnet at a distance of 4 cm		PASS

In addition, for the external magnetic controller, the use life was determined to be 25 uses based on accelerated aging, as demonstrated in Table 9 below.

Table 9: Magnetic Controller Use Life Testing

Magnetic Controller Use Life Testing after 25 Uses	Acceptance Criteria	Results
Tensile test	Encasement can be suspended by the upper edge b(4) without breakage	PASS
Visual Inspection	After cycling and suspension, no defects that would compromise integrity	PASS

Bench testing demonstrated that the device performs as expected under anticipated conditions of use.

PERFORMANCE TESTING – ANIMAL

As described in detail in Table 9, an animal study was conducted to support that the Levita Magnetic Surgical System performs as expected under anticipated use conditions.

Table 10: *In Vivo* Animal Study

Title:	Levita Magnetic Surgical System Animal Safety and Performance Study
Study Objective:	• Evaluate the effects of the Magnetic Surgical System when used in thin-abdominal wall subjects, specifically when using the Magnetic Controller to change position of the Detachable Grasper for purposes of tissue manipulation when the Magnetic Controller and the Detachable Grasper are both in contact with the abdominal wall; • Evaluate the performance of the Magnetic Surgical System when used during single-incision laparoscopic cholecystectomy surgery; • Evaluate the Magnetic Surgical System's compatibility with laparoscopic instrumentation and operating room equipment, specifically monopolar, bi-polar and ultrasonic harmonic instrumentation
Study Endpoints:	• Safety was assessed by evaluation of the effects of the Magnetic Surgical System on the abdominal wall and abdominal tissue/organs. The effects were determined grossly by a pathologist and microscopically by an independent histopathologist. • Performance was assessed by the evaluation of the Magnetic Surgical System when used in single incision laparoscopic cholecystectomy, compatibility of the Magnetic Surgical System with the instrumentation and equipment used during the procedure, and ability to retrieve the Detachable Grasper. A clinical evaluator experienced in single-incision laparoscopy conducted the evaluation.
Study Design:	Two canines underwent a single-port laparoscopic cholecystectomy procedure; an intentional maximum force repeated dragging of the Detachable Grasper over a section of abdominal wall, and an intentional dropping and retrieval of the Detachable Grasper into and from the abdominal cavity. To assess their compatibility, multiple types of electrosurgical equipment were used during the laparoscopic cholecystectomy. Canines were chosen for their abdominal wall thickness, which represents worst-case (thin) human abdominal walls of 0.5cm to 1.0cm. The minimum human abdominal wall thicknesses in the published study referenced above were 5mm and 10mm, for the umbilicus and left upper quadrant, respectively.

Results:	The Magnetic Surgical System was utilized to manipulate the gallbladder for several cycles using the Magnetic Controller, without any adverse events. The sponsor states that their experience with the Magnetic Surgical System in this study suggests the ability to control the devices within the abdominal cavity using a magnet external to the body. The sponsor also states that based on user feedback there is the ability to have minor haptic feel without controlling the internal device via a shaft. This haptic feel is limited to drag sensation when retracting the body or fundus of the gallbladder with the external magnet while coupled to internal detachable grasper. The minor haptic feel does not provide feedback in regards to the changes in the grasping of gallbladder tissue with manipulation of the gallbladder and progress of the surgery. The gross pathological findings demonstrated that there was no evidence of clinically relevant trauma to the abdominal wall associated with the test articles. The observations noted were minimal and the defects caused by the control 5mm trocar were much more severe as compared to the test site. The findings resulting from the placement of a 5mm trocar typically used in laparoscopic procedures demonstrate obvious full body wall thickness trauma, including hemorrhage. Moreover, the histopathological findings demonstrate that there were no significant increases in trauma associated with the test article when compared to a 5mm trocar. The safety endpoint acceptance criteria for intra-procedural adverse events, gross pathology, and histopathology evaluation were met. In the performance evaluation, the Magnetic Surgical System was employed to complete a single-incision laparoscopic cholecystectomy. The performance endpoint acceptance criteria for the completion of a laparoscopic cholecystectomy and compatibility with equipment/instrumentation were met. In summary, all study objectives were successfully met.

PERFORMANCE TESTING – HUMAN FACTORS

The sponsor conducted human factors validation testing using a training didactic presentation prior to testing the participants, 15 surgeons at 2 different sites. Simulated use environment testing was used to assess the effectiveness of the proposed commercial training program and if it facilitates safe use of the device. Simulated use environment was used since it is possible to engage more users in more use scenarios in a limited amount of time as compared to a clinical study.

The sponsor trained the surgeons using the Instructions for Use, device labels, patient screening checklist, and a training presentation. All subjects were trained face-to-face using the training presentation and the hands-on demonstration described in the presentation. The sponsor has developed a training didactic presentation that follows the Instructions for Use to train for correct use of the system. The training presentation includes sections on safe use of the device, contraindications, warnings, precautions, potential adverse events, patient selection, instructions for use, and hands-on practice. Training groups consisted of 3-4 test subjects and they completed all aspects of the study, including the pre-simulation questionnaire, all three scenarios of the simulation, and the post-simulation questionnaire. The acceptance criteria were no critical failures (Critical

Task Errors detailed below in Table 8) and no more than two non-critical failures per subject (any failures with the tasks written below not indicated as critical tasks). Tasks performed after reading the User Manual and Training during the Human Factors assessment included:

- User removes Magnetic Grasper Device from packaging places in sterile field
- User performs inspection of Magnetic Grasper Device functionality
- User removes Magnetic Controller from case
- User performs inspection of Magnetic Controller (critical task)
- User wipes down Magnetic Controller (critical task)
- User covers Magnetic Controller with sterile bag (critical task)
- User inserts Magentic Grasper Device into 100 mm or larger port under laparoscopic visualization (critical task)
- User advances and maneuvers Magnetic Grasper Device towards tissue
- User opens Magnetic Grasper jaws by retracting handle thumb lever
- User engages tissue with open Magnetic Grasper jaws
- User closes Magnetic Grasper jaws upon tissue by advancing handle thumb lever to default position
- User decouples Detachable Grasper from Delivery/Retrieval Shaft of the Magnetic Grasper Device by advancing handle thumb lever to forward position
- User moves Magnetic Controller to abdominal area to attract Detachable Grasper towards abdominal wall
- User positions Magnetic Controller at distance from abdomen to result in "Acceptable Contact" of the Detachable Grasper with the abdominal wall
- User adjusts Magnetic Controller's position to appropriately lift and retract the tissue
- In the event of unintended decoupling of the Detachable Grasper from the Magnetic Controller, user recouples the Detachable Grasper to the Magnetic Controller using appropriate instruments
- In the event of a lost or hidden Detachable Grasper, user retrieves Detachable Grasper with appropriate instruments (critical task)
- User retrieves Detachable Grasper and removes Detachable Grasper from abdomen through port (critical task)
- User removes sterile bag from Magnetic Controller and cleans/disinfects Magnetic Controller (critical task)
- User disengages Magnetic Controller from optional off-the-shelf positioning arm and returns Magnetic Controller to carrying case
- User returns Magnetic Controller to storage

The following table (Table 11) identifies the possible device use-related hazards due to the critical tasks (indicated above) and their respective mitigations.

Table 11: Critical Task Errors

Critical Task Error	Hazard(s) Resulting from Error	Severity	Mitigations
User fails to perform inspection of Magnetic Controller	• Malfunctioning device used in procedure, injury to patient or user	3	• Inspection instructions in IFU • Physician Training
User fails to wipe down Magnetic Controller	• Contamination	4	• Device preparation instructions in IFU • Warnings and Precautions in IFU. • Physician Training
User fails to cover Magnetic Controller with sterile bag	• Infection	4	• Device preparation instructions in IFU • Physician Training
User inserts Grasper without laparoscopic visualization	• Intra-abdominal tissue trauma	3	• Instructions on device insertion in IFU • Warnings and Precautions in IFU • Physician Training
In the event of a lost or hidden Detachable Grasper, user attempts to retrieve Detachable Grasper using Magnetic Controller	• Tissue trauma/injury	4	• Instructions on retrieval in IFU • Warning statement in IFU • Physician Training
User fails or is unable to retrieve Detachable Grasper and remove from abdomen through port	• Tissue trauma • Injury from larger incision	3	• Retrieval and removal instructions in IFU • Physician Training
User fails to clean/disinfect Magnetic Controller	• Infection	4	• Cleaning/Disinfection instructions in IFU • Physician Training

This Human Factors study assessed the ability of surgeons to operate the Magnetic Surgical System after training with no critical errors and no more than two non-critical errors after participating in a training regarding these devices. All 15 test subjects passed all tests without any critical or non-critical errors.

SUMMARY OF CLINICAL INFORMATION

As described in detail in Table 12, a clinical study was conducted to support that the Levita Magnetic Surgical System performs as expected under anticipated use conditions.

Table 12: Clinical Study Data

Title:	Levita Magnetic Surgical System Safety and Performance Study
Study Objective:	The first study was to evaluate the preliminary safety and feasibility of the Levita Magnetic Surgical System in the treatment of patients undergoing laparoscopic cholecystectomy for benign gallbladder disease Second study was a pivotal study to evaluate safety and effectiveness of the Levita Magnetic Surgical System in the treatment of patients undergoing laparoscopic cholecystectomy for benign gallbladder disease
Study Design:	Prospective, single arm, open label study (both feasibility and pivotal) designed to assess the safety and device performance of the Levita Magnetic Surgical System. All patients were expected to undergo post-operative pain evaluation, cosmesis, and quality of life assessments. Appearance of the post-operative scar and patients overall satisfaction with the procedure were evaluated.

Enrollment Size and Number of Sites:	Levita performed their feasibility study with 21 patients and had a second single-armed pivotal study with 50 patients conducted in three (3) sites in Chile
Patient Population:	All patients between 18 and 60 yrs of age, presenting with benign gallbladder disease who are eligible for laparoscopic cholecystectomy were potential candidates
Number of Subjects	Feasibility Study: 22 enrolled, 21 subjects underwent surgery Pivotal Study: 50 subjects underwent surgery
Primary Safety Endpoints:	Absence of any damage or side effect to the patient directly produced by the device during the surgery defined as: 1. There is no evidence of a Device Failure defined as device breakage or other malfunction requiring additional surgical intervention including reoperation and/or device removal. 2. There is no Serious Adverse Event probably or definitely related to the grasping and tissue manipulation procedure or to the device resulting in: (a) revision/removal of device; and/or (b) permanent damage to the organ (i.e. perforation of the gallbladder or surrounding organs), (c) death of the study subject. Overall morbidity rate defined as occurrence of any complications directly or indirectly related to the investigational device assessed intra-operatively, post-operatively and at 30 day follow-up occurring within 30 days of surgery.
Primary Feasibility Endpoint:	Ability to adequately mobilize the gallbladder to achieve an effective exposure of the target tissue. *Feasibility will be considered a "failure" if during the procedure, it becomes necessary to use another trocar to insert another instrument to mobilize the gallbladder.
Other Outcome Assessments:	• Operative time (time from the first incision to the last suture's placement) • Device use time (time of coupling between the internal grasper and the external magnetic controller) • Time spent in Post-anesthesia care unit (PACU) • Length of stay (LOS) (time from post-anesthesia care unit until discharge) • Perioperative pain as measured on a Numeric Rating Scale (NRS) at pre-op (baseline), 3 and 6 hours post-op and discharge (24 hour post-op assessment will be done if patient is not discharged) and at 7 and 30 day follow-up • Pain medication usage while in PACU and until hospital discharge • Conversion rate (reduced port to 4-port) • Blood loss • Umbilical incisional length • Access site herniation • Patient satisfaction with the overall procedure based on patient survey at 30 day follow-up • Ease of use based on surgeon assessment post-operatively • Cosmesis or scarring (patient and surgeon assessed satisfaction survey) at 7 and 30 day follow-up • Final post-operative diagnosis
Inclusion Criteria:	• Patient between 18 and 60 years of age • Undergoing elective cholecystectomy due to: o Cholelithiasis (Gallbladder stones < 2.5cm in longer measurement (length or width))

	○ Gallbladder polyps as assessed by ultrasound • Absence of non-correctable coagulopathy (INR < 1.4 or, platelet count of < 50,000/mcl) • Patient has a body mass index (BMI) ≤ 34 kg/m^2 and over 20 kg/m^2 • Patient, or authorized representative, signs a written Informed Consent form to participate in the study, prior to any study mandated determinations or procedure
Exclusion Criteria:	• Emergency presentation with acute gallbladder disease • Clinical suspicious of Pancreatitis • Jaundice • Scleroatrophic gallbladder as shown by ultrasound • Biliary tract stones diagnosed before or during surgery • Acute cholecystitis • Gallbladder Empyema • Ongoing peritoneal dialysis • Previous abdominal surgery or laparotomy (presence of any previous upper umbilical incision) • Presence of umbilical hernia or previous umbilical hernia • American Society of Anesthesiologists (ASA) score of III or IV • Patient is undergoing treatment for chronic pain of any origin • Significant comorbidities: cardiovascular, neuromuscular, chronic obstructive pulmonary disease, and urological disease (renal failure) • Patients with signs of gallbladder perforation diagnosed by ultrasound • Suspicion of biliary cancer • Patients with severe peritonitis • Contraindications to pneumoperitoneum • Known allergy to paracetamol or NSAIDs • Patients with metallic implants (such as pacemakers, prosthesis, etc) • Previously diagnosed or suspected of having a history of choledocholithiasis based on any alterations in plasma hepatic enzymes • Has a biliary tract > 7mm in size as determined by ultrasound • Has a gallbladder wall thickness that is > 5mm • Diabetic • Blood coagulation issues • Has signs of hepatic endocrinology (i.e: cirrhosis, liver failure, increase in liver enzymes, etc.) • History of endoscopic papillotomy (i.e: Preoperative indication of endoscopic retrograde cholangiopancreatography (ERCP) • Patient is pregnant or wishes to become pregnant during the length of study participation or lactation • Patient is not likely to comply with the follow-up evaluation schedule • Patient is participating in a clinical trial of another investigational drug or device • Patient is mentally incompetent or a prisoner

	• Known or suspected drug or alcohol abuse • Patient has systemic infection or evidence of any surgical site infection (superficial or organ space) • Patient has compromised immune system or autoimmune disease (WBC < 4000 or > 20,000), including prior or pending treatment for HIV or Hep. C • Patient intra-operatively needs an additional surgery while undergoing elective cholecystectomy
Study Duration / Follow-up Period	Patients were followed for a maximum of 30 days post-procedure, with follow-up visits at hospital discharge and at 7 and 30 days post-procedure.

Results:

The safety results met the criteria outlined for the primary safety endpoint for this study, because there were no cases of a device failure. Device failure is defined as device breakage or other malfunction requiring additional surgical intervention including reoperation and/or device removal. Three (3) serious adverse events and thirty-five (35) non serious AEs were reported throughout the course of the study. No severe or serious adverse events were found to be device-related. Twenty (20) device-related events were noted. The device-related events were categorized as mild petechiae that were observed during the index procedure. The observed petechiae were mild and were not considered clinically significant by the study investigators, as all events resolved with no clinical sequelae. The mild petechiae reported represent much less trauma to the tissue than would be the case with a trocar insertion. This is a single arm study and patient survey indicated that over 90% of the patients were satisfied on postoperative day 7 and 30.

The device performance results met the criteria outlined for the primary performance endpoint for this study, because in all cases the device was able to adequately mobilize the gallbladder to achieve an effective exposure of the target tissue. While an additional trocar was placed in one procedure, this additional trocar was not needed to mobilize the gallbladder and this trocar was placed after the Magnetic Grasper device use was complete and removed from the abdomen. As a result, no additional trocars were placed to insert another instrument to mobilize the gallbladder.

The results show that the Magnetic Surgical System can be used in laparoscopic cholecystectomy procedures in subjects with varying abdominal wall thicknesses (1.8 – 4.6 cm) that correspond with a range of BMIs (20.4 – 34.1 kg/m2). Additionally, the device can be used to facilitate three-port cholecystectomy procedures in a manner that provides adequate exposure and mobilization of the target tissue. The average overall procedure time was 63 minutes and the amount of coupling time between the Magnetic Controller and the Magnetic Detachable Grasper was 34 minutes. All procedures were completed with no conversions to an open surgical approach required. Importantly, the Magnetic Surgical System was used in a standard operating room with conventional electrosurgical equipment and no device malfunctions or equipment interferences were reported.

LABELING

Labeling has been provided, which includes the instructions for use and an appropriate prescription statement as required by 21 CFR 801.109.

The sponsor has provided the magnetic field strength testing results, including tables detailing the magnetic safe zones, in the User Manual and on the external magnetic controller carrying case. In addition, the sponsor has included a Screening Checklist to ensure that all patients and Operating Staff are screened from bringing ferromagnetic implants, devices or objects near the external magnet. These magnetic safe zones tables and the Screening Checklist mitigate the risk of electromagnetic field incompatibility or interference.

The sponsor has provided detailed instructions for proper device use, which mitigate the risks of tissue damage, need for extended or additional surgery, abdominal wall injury, and electromagnetic field incompatibility or interference.

The sponsor has included sterilization, cleaning and disinfection instructions, along with determined shelf life, which mitigate the risk of infection.

RISKS TO HEALTH

Table 13 identifies the risks to health that may be associated with use of the Magnetic Surgical Instrument System and the measures necessary to mitigate these risks.

Table 13: Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Tissue Damage	• *In vivo* Performance Testing • Human Factors Testing and Analysis • Training • Labeling
Need for Extended or Additional Surgery: • Inability to couple the external magnet with the internal surgical instrument • Inability to retrieve or maneuver device • Inability to visualize critical anatomical structures	• *In vivo* Performance Testing • Non-clinical Performance Testing • Human Factors Testing and Analysis • Training • Labeling
Abdominal Wall Injury	• *In vivo* Performance Testing • Human Factors Testing and Analysis • Labeling
Electromagnetic Field Incompatibility or Interference (including ferromagnetic implants in users and patients, electrosurgical devices, etc.)	• Non-clinical Performance Testing • Human Factors Testing and Analysis • Training • Labeling
Adverse Tissue Reaction	• Biocompatibility Evaluation

Identified Risk	Mitigation Measures
Infection	• Sterilization Validation • Reprocessing Validation • Shelf Life Validation • Labeling

SPECIAL CONTROLS:

In combination with the general controls of the FD&C Act, the Magnetic Surgical Instrument System is 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.

BENEFIT/RISK DETERMINATION

The risks of the Levita Magnetic Surgical System are based on nonclinical laboratory and animal studies as well as data collected in the clinical studies described above. One such risk could be diminished haptic feedback, which can result in applying to much force on the gallbladder wall resulting in tearing of the wall with bile and stone spillage. In the animal and clinical study, based on user feedback, there was some haptic feedback in dragging the external magnetic controller which also moves the internal detachable grasper when coupled.

One minor risk is the abdominal wall injury, such as petechiae. Twenty (20) device-related events were noted in the clinical study. The device-related events were categorized as mild petechiae that were observed during the index procedure. The observed petechiae were mild and were not considered clinically significant by the study investigators, as all events resolved with no clinical sequelae. In addition, the mild petechiae reported represent much less trauma to the tissue than would be the case with a trocar insertion.

Another probable risk includes device usage in a contracted inflamed gallbladder may not provide ideal anatomic exposure and may require additional training to mitigate anatomic and pathologic variations in the gallbladder when using this device. Traditional laparoscopic graspers frequently require additional force and torque to achieve adequate exposure. The manipulation of this grasper in removing the gallbladder from the liver bed requires surgeon action and fundus response. However, this issue has been mitigated within the labeling by preventing the use of this device in difficult situations, such as "if adhesions, stones, or fibrosis interfere with exposure of the critical view of safety or definition of the components of the hepatocystic triangle". In addition, acute decoupling of the controller magnet and the grasper at critical points in surgery can be difficult to re-establish and the loss of exposure can result in injury. This is mitigated in the labeling by including language that explains that steps to re-establish coupling between the detachable grasper and the magnetic controller. Also, another risk involves injury resulting from recovery of loss of the detachable grasper in the abdominal cavity. However, this has been mitigated in the labeling by providing a safe and tested method of retrieving a lost detachable grasper and cautioning against doing it improperly.

The probable benefits of the device are also based on nonclinical laboratory and animal studies as well as data collected in the clinical studies as described above. The device allows for one less 5 mm port in the performance of laparoscopic cholecystectomy. This should result in several probable benefits. Since the studies presented were single armed, comparisons could not be made due to lack of a traditional laparoscopic cholecystectomy control. However, the subject device presents a novel method of providing surgical retraction that may provide a stepping stone to future minimally invasive surgical procedures. Such probable benefits include fewer episodes of inadvertent trocar injuries of intra-abdominal organs and structures within the abdominal wall (nerves and blood vessels), fewer episodes of instrument crowding, and one less abdominal wall scar resulting in better cosmesis.

The Levita Magnetic Surgical System, while providing tangible benefits, may be difficult to use by a surgeon who has not been familiarized with it prior to using it for the first time. A robust training program should overcome any learning curve that may exist.

Patient Perspectives

Although not a primary outcome of the clinical study conducted, a patient survey was completed as an additional assessment. The survey indicated that over 90% of the patients were satisfied on postoperative days 7 and 30.

Benefit/Risk Conclusion
Given the information submitted in the *de novo* request, the data support that for the indication of "grasping and retracting the body and the fundus of the gallbladder in laparoscopic cholecystectomy procedures to facilitate access and visualization of the surgical site", the probable benefits outweigh the probable risks for the Levita Magnetic Surgical System. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The *de novo* request for the Levita Magnetic Surgical System is granted and the device is classified under the following:

Product Code: PNL
Device Type: Magnetic Surgical Instrument System
Class: II
Regulation: 21 CFR 878.4815