DE NOVO CLASSIFICATION REQUEST FOR MAGDI™ SYSTEM

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Magnetic compression anastomosis system.** A magnetic compression anastomosis system is a surgical device used for the creation of anastomoses in minimally invasive and laparoscopic surgery in the gastrointestinal tract. The system is comprised of magnet devices and may involve a delivery system. Compression and necrosis of tissue between magnet devices is created by polar attraction of the magnet devices with healing of tissue around the devices. Once the anastomosis is formed, the magnet devices are expelled naturally. This classification does not include devices intended for weight loss or metabolic disease treatment.

NEW REGULATION NUMBER: 21 CFR 878.4816

CLASSIFICATION: Class II

PRODUCT CODE: SAH

BACKGROUND

DEVICE NAME: MagDI System

SUBMISSION NUMBER: DEN240013

DATE DE NOVO RECEIVED: March 26, 2024

SPONSOR INFORMATION:

GT Metabolic Solutions, Inc.
5450 Quam Ave NE, Suite 100
St. Michael, Minnesota 55376

INDICATIONS FOR USE

The MagDI System is indicated as follows:

> The GT Metabolic MagDI System is intended for use in the creation of side-to-side duodeno-ileal anastomoses in minimally invasive and laparoscopic surgery. Once wound strength is sufficient to maintain the anastomosis, the device is passed from the body. The effects of this device on weight loss were not studied.
>
> The GT Metabolic MagDI System is intended for use in adult patients > 21 years.

LIMITATIONS

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

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

DEVICE DESCRIPTION

The MagDI System is comprised of two (2) GT Metabolic DI Magnet ("Magnet") devices delivered sequentially with a minimally invasive GT Metabolic Delivery System ("Delivery System"). Class I magnetic surgical instruments (GT Metabolic Laparoscopic Positioning Device; FDA Listing #D512834) are used to position the Magnets to the target anastomosis locations in the duodenum and ileum and connect the two Magnets. The device provides a method for the creation of a round (oval/circular) compression anastomosis.

After a period of approximately 7-21 days, a compression-induced necrosis of the tissue between the Magnets occurs and the whole device, together with the necrosed tissue that was compressed by the Magnets, detaches, and is naturally expelled with the stool.

The MagDI System components (Magnets and Delivery System), as shown in Figures 1 and 2 below, are provided sterile and are for single use.

Figure 1: GT Metabolic DI Magnet Assembly (left), Attachment [Tube Assembly] (right)

Figure 2: Delivery System with Magnet Attached

SUMMARY OF NONCLINICAL/BENCH STUDIES

PERFORMANCE TESTING - BENCH

The MagDI System underwent design verification testing (DVT) to ensure package integrity and device performance as described **Table 1**. The Magnets and Delivery System passed all testing demonstrating the device performs as expected under anticipated conditions of use. All testing occurred on units that were pre-conditioned per the requirements of recommended international standards to substantiate distribution and a prescribed shelf life.

Table 1: Summary of Nonclinical/Bench Studies:

Test	Purpose	Methods / Standard	Acceptance Criteria	Results
Visual Inspection, Product Packages (Magnet/Delivery System)	Visual inspection for gross physical defects.	Visual inspection for gross physical defects.	No obvious damage. All seals must be intact. Labels must be readable by human eye and barcode scanner.	Pass
Visual Inspection, Package / Device (Magnet/Delivery System)	Visual inspection for gross damage.	Peel pouch, verify product retention within packaging, inspect product for gross visual damage.	The pouch must peel consistently. Product removes from pouch easily. No damage or defects to the device.	Pass
Device Inspection	Inspection for damage to the device.	Visual inspection for damage and anomalies.	No damage to the device. Magnet Suture intact.	Pass
Magnet Separation Force	Demonstrate product integrity following conditioning.	Measure separation force.	(b)(4)	Pass
Assembly Pull Test (Magnet/Delivery System)	Demonstrate product integrity following conditioning.	Tensile loading and unloading force cycle without the Magnets disengaging or damage/failure of any joints of the entire system.	(b)(4)	Pass
Simulated Use (Magnet/Delivery System)	Demonstrate product integrity following conditioning.	The Delivery System loaded with the Magnet must be navigated through a tortuous path.	Reach target, deploy magnet, and withdrawal. Slide deployment force (b)(4)	Pass
Suture Loop Pull Test (Magnet)	Demonstrate product integrity following conditioning.	Force test assembly at a fixed rate.	(b)(4)	Pass
Assembly Torque Test (Magnet)	Demonstrate product integrity following conditioning.	Torque test assembly to fixed position.	(b)(4)	Pass
Package Test, Bubble Leak (Magnet/Delivery System)	Demonstrate product and package integrity following conditioning.	ASTM F2096	Pouches must not show evidence of seal or channel leakage.	Pass
Package Test, Peel Strength (Magnet/Delivery System)	Demonstrate product and package integrity following conditioning.	ASTM F88	Peel strength must be (b)(4) (b)(4)	Pass

Test	Purpose	Methods / Standard	Acceptance Criteria	Results
Delivery System Pull Pin Test	Demonstrate product integrity following conditioning.	Tensile and compression test Delivery System Pin	(b)(4)	Pass
Crimped Weld Pull Test (Delivery System)	Demonstrate product integrity following conditioning.	Tensile test mechanical connection.	(b)(4)	Pass

BIOCOMPATIBILITY/MATERIALS

Biocompatibility for the MagDI System was assessed according to FDA's Biocompatibility Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff. All patient-contacting components of the MagDI System passed per ISO 10993-1.

Table 2: Magnet Materials, Type and Duration of Contact

Material	Type and Duration of Contact (ISO 10993-1)
• Titanium (Ti-6AI-4V ELI, Grade 23) alloy • Parylene C-coated neodymium-iron-boron (NdFeB) magnet • 304 stainless steel • 316 stainless steel • Nitinol wire • Tevdek® (PFTE-coated polyester) braided suture • Loctite® 4011 Instant Adhesive (cyanoacrylate)	Type of Contact: Surface Mucosal membrane Duration of Contact: Long-term (> 30 days)

Table 3: Biocompatibility Testing Summary for Magnets

Test Performed	Test Method	Results
Cytotoxicity MEM Elution	ISO 10993-5: MEM Elution Study used to evaluate device extracts for cytotoxicity risks.	Pass – non-cytotoxic
Skin Sensitization	ISO 10993-10: Guinea Pig Maximization Sensitization Test used to evaluate device extracts for dermal sensitization risks	Pass – not a sensitizer
Intracutaneous Irritation	ISO 10993-23: Intracutaneous Irritation Test used to evaluate device extracts for irritation risks	Pass – non-irritant
Acute Systemic Toxicity	ISO 10993-11: Acute systemic toxicity study used to evaluate device extracts for systemic toxicity risks	Pass – no signs of systemic toxicity
Material-Mediated Pyrogenicity	ISO 10993-11: Rabbit pyrogen test used to evaluate device extracts for pyrogenicity risks.	Pass – non-pyrogenic
Subacute / Subchronic Toxicity	ISO 10993-11: Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity	Pass – no signs of subchronic systemic toxicity
Genotoxicity (Ames Assay/ Mouse Lymphoma Assay)	ISO 10993-3: Biological Evaluation of Medical Devices Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity.	Pass – non-mutagenic

Test Performed	Test Method	Results
Implantation	ISO 10993-6: Biological Evaluation of Medical Devices - Part 6: Tests For Local Effects After Implantation	Pass – See Performance Testing - Animal
Chronic Toxicity	ISO 10993-11: Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity	Pass – See Performance Testing - Animal

Table 4: Delivery System Materials, Type and Duration of Contact

Material	Patient Contact and Duration (ISO 10993-1)
• Nitinol • 304V stainless steel • Hytrel® (DuPont polymer) 55D / 82D	Type of Contact: Surface Mucosal membrane Duration of Contact: Limited (≤ 24 hrs.)
• 18-8 stainless steel • 316 stainless steel • PEEK™ • 304 stainless steel	Type of Contact: Non-patient contacting

Table 5: Biocompatibility Testing Summary for Delivery System

Test Performed	Test Method	Results
Cytotoxicity MEM Elution	ISO 10993-5: MEM Elution Study used to evaluate device extracts for cytotoxicity risks.	Pass – non-cytotoxic
Skin Sensitization	ISO 10993-10: Guinea Pig Maximization Sensitization Test used to evaluate device extracts for dermal sensitization risks	Pass – not a sensitizer
Intracutaneous Irritation	ISO 10993-23: Intracutaneous Irritation Test used to evaluate device extracts for irritation risks	Pass – non-irritant

SHELF LIFE/STERILITY

Shelf-life testing comprised of aging the MagDI System and then performing the design verification testing (see **Table 1: Performance Testing - Bench**).

The MagDI System (Magnet and Delivery System) was fully validated for sterility via gamma irradiation per ISO 11137-1 – Sterilization of Health Care Products – Radiation. All package integrity testing related to sterility was tested as part of the design verification testing (see **Table 1: Performance Testing - Bench**) All testing occurred on units that were pre-conditioned per the requirements of recommended international standards to substantiate distribution and a prescribed shelf life.

ELECTROMAGNETIC CAPABILITY & ELECTROMAGNETIC SAFETY

The MagDI System is not a medical electrical device, so the IEC 60601-1 technical standard and associated electrical, mechanical, and thermal safety testing does not apply.

The MagDI System utilizes magnetic technology to produce mechanical compression for the anastomosis. Static magnetic field strength testing was conducted on the Magnets and evaluated against the thresholds set by the National Institute of Standards and Technology (NIST[1]) and the International Commission on Non-Ionizing Radiation Protection (ICNIRP[2]) for occupational exposure, the general public, and medical device wearers. The testing demonstrated that the static magnetic field strength of two connected Magnets rapidly decays to well below 5 gauss at a distance of 1.5 inches. The exposure for intended users remains significantly below the identified thresholds and appropriate mitigation for patients has been incorporated in the instructions for use (IFU), including contraindication for use in patients with implantable devices or other metal and MR unsafe labeling.

References:

1. National Institute of Standards and Technology (NIST), U.S. Department of Commerce. Magnetic Field Safety. NIST S 7101.53. Document Approval Date: 01/05/2021. Downloaded 04MAR2024, https://www.nist.gov/oshe/safety-programs/magnetic-field-safety-program.
2. International Commission on Non-Ionizing Radiation Protection (ICNIRP). ICNIRP Guidelines on Limits of Exposure to Static Magnetic Fields. Published in Health Physics; 2009. 96(4):504-514. http://www.icnirp.org/cms/upload/publications/ICNIRPstatgdl.pdf.

MAGNETIC RESONANCE (MR) COMPATIBILITY

The MagDI System is MR unsafe.

SOFTWARE

The MagDI System does not contain software.

PERFORMANCE TESTING - ANIMAL AND/OR CADAVER

Development and verification porcine studies (n=9; see **Tables 8 and 9**) over 6 weeks were conducted for the MagDI System with a comparison to sutured enterotomies as a proxy for the conventional hand-sutured anastomotic technique.

Table 8: Porcine Developmental study

Evaluation of a Magnetic Anastomosis Devices in a Swine Model over 6 Weeks
Study Type and Objective: Porcine (n=5) developmental study. To evaluate the feasibility and safety of the side-to-side anastomosis procedure. The hybrid pig small bowel has a shorter duodenum and ileum compared to jejunum than in the human. Thus, this animal study procedure created a duodeno-jejunal anastomosis that represents the duodeno-ileal anastomosis procedure in the clinical study. **Follow-up Duration:** 6 weeks (41-42 days)
Procedure: • Side-to-side magnetic duodeno-ileostomy was performed with both magnetic anastomosis devices delivered endoscopically (by gastroscope) or by an intestinal incision via laparotomy or laparoscopy.
Safety Outcomes: • One (1) out of the five (5) animals had an internal hernia that resulted in death on Day 4. The death was

determined to be procedure related and was diagnosed as hypovolemic shock due to entrapment of a large section of the jejunum in a mesenteric defect (internal hernia) and not related to the device.

- The device was released into the lumen from the anastomotic site at a mean of 12.5 days (range 10-14 days) with peri-anal expulsion occurring at a mean of 23.7 days (range 13-34 days) (n=4 animals).
- Animals continued an expected growth (weight gain) path.
- Patent anastomoses were observed in the animals (n=4).

Conclusions:

- The MagDI System successfully induced a duodeno-ileal anastomosis in pigs when placed surgically and endoscopically. They were well tolerated clinically and were associated with a good healing response when evaluated microscopically, characterized by low levels of inflammation and tissue disruption and absence of adhesions at the placement sites at 6 weeks post-operatively.
- Although one (1) animal died due to an internal hernia, the death was determined to not be related to the MagDI System, but due to the surgical procedure. Closure of mesenteric defects in swine is impractical, as the mesentery is paper thin and sustains hemorrhage and hematoma when attempting closure with sutures, a task that can normally be performed successfully in humans with much less difficulty to reduce the risk of mesenteric internal hernias.[1,2]

Table 9: Porcine Verification Study

Evaluation of a Magnetic Anastomosis Devices in a Swine Model over 6 Weeks
Study Type and Objective: Porcine (n=4) verification study. Evaluation of the feasibility and efficacy of a magnetic anastomosis device delivered surgically and endoscopically to create a side-to-side anastomosis in a swine model over 6 weeks. The hybrid pig small bowel has a shorter duodenum and ileum compared to jejunum than in the human. Thus, this animal study procedure created a duodeno-jejunal anastomosis that represents the duodeno-ileal anastomosis procedure in the clinical study. **Follow-up Duration:** 6 weeks (41-42 days)
Procedure: • Side-to-side magnetic duodeno-ileostomy was performed with both magnetic anastomosis devices delivered endoscopically (by gastroscope) or by an intestinal incision via laparotomy or laparoscopy. The magnets were positioned and moved to the final anastomosis site using a Laparoscopic Positioning Device.
Safety Outcomes: • The device was released into the lumen from the anastomotic site at a mean of 16 days (range 12-22 days) with peri-anal expulsion occurring at a mean of 24.5 days (range 17-33 days). • All animals continued an expected growth (weight gain) path. • Patent anastomoses were observed in all the animals. • Minor observations of abdominal adhesions were made in 2 of the 4 animals. This observation is consistent with humans who have had abdominal surgery. • The anastomoses created by the magnets were observed to be fully neovascularized and free of surgical injury, granuloma, and scarring. By comparison, the jejunal enterotomy (performed to compare sutured tissue to the magnet anastomosis tissue) exhibited normal surgical injury characterized by scarring. These observations were replicated histologically, where the remodeled tissue at the anastomosis more closely resembles minimally disturbed tissue.
Conclusions: Use of a magnetic compression anastomosis system to induce a duodeno-ileal anastomosis was associated with a good healing response characterized by low levels of inflammation and minimal tissue reaction as well as good vascularization at the site of device placement at 6 weeks post-operatively. These observations are in agreement with prior studies that conclude the establishment of anastomoses by compression is as effective and safe as those established by sutures or staples.[3] The company's surgical advisors recommend closure of mesenteric defect(s) to decrease the likelihood of an internal hernia with associated intestinal obstruction. Occurrence of mesenteric defects is a well-known complication in laparoscopic bariatric surgery[4] and can be addressed with standard techniques in humans.

The subject device was successfully placed (with appropriate alignment of two Magnets) and created patent anastomoses in all (100%, 9/9) of the duodeno-jejunal cases in the porcine studies. This testing location is representative of the small bowel (comprised of duodenum, jejunum, and ileum) as the duodenum is the most challenging portion of the small bowel given its proximity to other organs (e.g., pancreas, gallbladder) and the jejunum and ileum are similar in structure and function.

Magnet devices were expelled per anus naturally as a connected set (Magnets connected together) without the need for surgical or other re-intervention to retrieve the devices. Visual inspection of the Magnets revealed indications of usage, such as minor scratches and

discoloration of the metal. All anastomoses were fully formed with healthy anastomotic tissue as documented by necropsy and histology. There were no cases of device migration as monitored by x-rays and no adverse events reported related to migration (e.g., bleeding, lesions, fistula) in the studies. This animal model, with direct comparison to the conventional suturing anastomotic technique, evaluates safe and effective use of the device to produce patent side-to-side anastomoses in the small bowel.

These animal study results are published in the literature:

Gagner M, Krinke T, Lapointe-Gagner M, and Buchwald JN. Side-to-side duodeno-ileal magnetic compression anastomosis: design and feasibility of a novel device in a porcine model. Surgical Endoscopy. 2023; 37: 6197-6207. https://doi.org/10.1007/s00464-023-10105-x.

References:

1. Comeau E, Gagner M, Inabnet W B, Herron D, M Quinn T M, Pomp A. Symptomatic internal hernias after laparoscopic bariatric surgery. Surgical Endoscopy. 2005; 19(1):34-39.
2. Stenberg E, Ottosson J, Magnuson A, et al. Long-term safety and efficacy of closure of mesenteric defects in laparoscopic gastric bypass surgery – A randomized clinical trial. JAMA Surgery. 2023;158(7):709-717. Doi:10.1001/jamasurg.2023.1042.
3. Brown W A, Ballesteros G P D, Ooi G, Higa K, Himpens J, Torres A, Shikora S, Know L, Herrera M F, IFSO appointed task force reviewing the literature on SADI-S/OADS. Obesity Surgery. 2021; 31:3-25, Diaz R, Davalos G, Welsh L K, Portenier D, Guerron A D. Surgical Endoscopy. 2019; Kallies K, Rogers A M, American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. Surgery for Obesity and Related Diseases. 2020; 16:825-830.

SUMMARY OF CLINICAL INFORMATION

Table 10: Summary of Clinical Study

Study Title	Creation of Side-to-Side Compression Anastomosis Using the GT Metabolic Solutions Magnetic Anastomosis System (MAGNET System) to Achieve Duodeno-Ileostomy Diversion in Adults with Obesity and with or without Type 2 Diabetes Mellitus: The MAGNET Study
Protocol Number / NCT Number: GTM-001 / NCT05322122	
Study Design	This is an operationally seamless, 2-stage, open-label, multicenter study enrolling up to 50 subjects at 5 study centers across Canada and Europe as follows: • **Stage 1** first-in-human (FIH) and proof-of-concept with 5 subjects; and • **Stage 2** feasibility with 45 subjects • All subjects in Stage 1 and 2 are followed for 12 months.
Study Population	Adults (18 to 65 years of age, inclusive) with obesity (BMI 30-50) who meet one of the following criteria: (1) have type 2 diabetes mellitus (T2DM) or experienced weight regain following previous sleeve gastrectomy; (2) have T2DM without previous sleeve gastrectomy; or (3) are candidates for a laparoscopic single anastomosis duodenal-ileal bypass with sleeve (SADI-S) procedure and have BMI ≥ 40.
Primary and Safety Endpoints	• **Primary: Feasibility/performance.** The side-to-side anastomosis duodeno-ileostomy will be considered feasible if results are successful at three months: • Placement of the MAGNET System (≥ 90% alignment of magnets); and • Passage of magnets without surgical re-intervention; and • Creation of a patent anastomosis, confirmed radiologically. **Safety:** Incidence of treatment emergent AEs.

A multi-center study was conducted to evaluate the feasibility/performance and safety of the MagDI System for the intended use in patients indicated for a side-to-side duodeno-ileal anastomosis. Forty-nine (49) subjects were treated across four (4) centers in Belgium, Canada, Republic of Georgia, and Spain.

Enrollment Criteria

Inclusion Criteria

Subjects eligible for enrollment in the study must meet all of the following inclusion criteria:

1. 18-65 years of age, inclusive, at the time of informed consent
2. BMI 30-50, inclusive with either:
    a. a. Previous-sleeve gastrectomy (> 12 months) with either T2DM (defined as HbA1c ≥ 6.5%) or weight regain; or
    b. b. T2DM without previous gastrectomy; or
    c. c. Undergoing laparoscopic single anastomosis duodenal-ileal bypass with sleeve (SADIS) where duodeno-ileostomy is performed side to side with the MAGNET System and BMI ≥ 40
3. Agrees to refrain from any type of additional bariatric or reconstructive surgery that would affect body weight for 1 year
4. If a child-bearing female, subject must commit to not becoming pregnant and agree to use contraception for 1 year
5. Willing and able to comply with protocol requirements

Exclusion Criteria

Subjects eligible for enrollment in the study must meet none of the following exclusion criteria:

1. Type 1 diabetes
2. Use of injectable insulin
3. Uncontrolled T2DM
4. Uncontrolled hypertension, dyslipidemia or sleep apnea
5. Prior intestinal, colonic or duodenal surgery, other than bariatric
6. Prior surgery, trauma, prostheses, disease or genetic expression which prevent or contraindicate the procedure, including scarring and abnormal anatomy.
7. Refractory gastro-esophageal reflux disease (GERD)
8. Barrett's disease
9. Helicobacter pylori positive and/or active ulcer disease
10. Large hiatal hernia
11. Inflammatory bowel or colonic diverticulitis disease
12. Any anomaly precluding orogastric access by gastroscope and catheters, and manipulation techniques.
13. Implantable pacemaker or defibrillator
14. Psychiatric disorder, except well-controlled depression with medication for > 6 mo, or history of substance abuse
15. Woman who is either pregnant or breast feeding
16. Woman of childbearing potential who does not agree to use an effective method of contraception.
17. Any comorbidity or current status of subject's physiological fitness that in the surgeon's or anesthesiologist's opinion represents safety concerns that make the subject medically unfit for the procedure. This includes any conditions for which endoscopic or laparoscopic surgery would be contraindicated, and any significant congenital or acquired anomalies of the GI tract at or distal to the placement of the magnets.
18. Unhealed ulcers, bleeding lesions, tumor or any other lesion at target magnet deployment site
19. Expected need for MR imaging within the first 2 months after the procedure
20. Any anomaly preventing/contraindicating laparoscopic access and general laparoscopic procedures
21. Had surgical or interventional procedure within 30 days prior to procedure
22. Any scheduled surgical or interventional procedure planned within 30 days post-procedure
23. Any stroke/TIA within 6 months prior to consent
24. Requires chronic anticoagulation therapy (except aspirin)
25. Active infections requiring antibiotic therapy, unless resolved before undergoing the study procedure
26. Unable to comply with the follow-up schedule and assessments
27. Recent tobacco or nicotine product cessation within < 3 months prior to informed consent
28. Known allergies to the device components or contrast media
29. Limited life expectancy due to terminal disease
30. Currently participating in another clinical research study with an investigational drug or medical device
31. A positive COVID-19 test prior to the study procedure

32. Any condition that, in the investigator's opinion, may preclude completion of follow-up assessments through Day 360 (e.g., a medical condition that may increase the risk associated with study participation or may interfere with interpretation of study results, inability to adhere to the visit schedule, or poor compliance with treatment regimen)

Table 11. Subject Enrollment by Site Location

Study Visit	Belgium	Canada	Republic of Georgia	Spain	Total
Enrolled and Treated n (% Total)	10 (20.5%)	24 (49%)	5 (10%)	10 (20.5%)	49 (100%)

Twenty-five subjects (51%, 25/49) received the study treatment only and 24 subjects (49%, 24/49) received the study treatment followed by a sleeve gastrectomy (SG) performed using standard practices at the institution (non-study procedure). Forty-two subjects (86%) have been followed to six months, 38 (78%) to nine months, and over half of the subjects (53%) to one year for study completion as of the date of data closure for the report (August 28, 2023). All subjects will be followed to one year per study protocol. Please see Table 12 for follow up information.

Table 12. Follow Up Progression by Procedure Cohort

Study Visit	MagDI System Procedure Only (n=25)[a]	MagDI System Procedure + SG (n=24)	All Subjects (n=49)
Study Procedure (D0) n (% cohort)	25 (100%)	24 (100%)	49 (100%)
Three months (D90) n (% cohort)	25 (100%)	24 (100%)[b]	49 (100%)[b]
Six months (D180) n (% cohort)	18 (72%)[c]	24 (100%)	42 (86%)[c]
Nine months (D270) n (% cohort)	14 (56%)	24 (100%)[c]	38 (78%)[c]
One year (D360) n (% cohort)	3 (12%)	23 (96%)[d]	26 (53%)[d]

[a]Subjects continue to progress through the study follow-up visit schedule, all subjects will be followed to one year.
[b]One subject missed D90 visit, but primary endpoint data was confirmed at a later visit for 100% confirmation of primary endpoint.
[c]One subject missed this study visit but attended subsequent visit for continued follow up.
[d]One subject exited study prior to completing D360 visit, but the investigator was able to gather data on clinical status.

Patient Demographics and Clinical Characteristics.

Tables 13 and 14 shows the subject demographics clinical characteristics respectively.

Table 13. Demographic Characteristics by Procedure Cohort

Characteristic	MagDI System Procedure Only subjects (n=25)	MagDI System Procedure + SG (n=24)	All subjects (n=49)
Age (Years)			
Mean (SD)	44.2 (7.9)	43.8 (9.0)	44.0 (8.4)

Min, Max	28 years, 57 years	28 years, 59 years	28 years, 59 years
Gender n (%)			
Female	24 (96%)	20 (83%)	44 (90%)
Male	1 (4%)	4 (17%)	5 (10%)
Race n (%) – patient self-report			
Caucasian	24 (96%)	18 (75%)	42 (86%)

It is notable that the study enrolled a subject cohort that consisted mostly of Caucasian and female participants. Based on this limited representation, there is moderate uncertainty of device efficacy when used in the targeted U.S. patient population.

Table 14. Baseline Clinical Characteristics by Procedure Cohort

Characteristic	MagDI System Procedure Only Subjects (n=25)	MagDI System Procedure + Sleeve Gastrectomy (n=24)	All Subjects (n=49)
Weight (kg) Mean (SD)	104.7 (21.1)	122.0 (16.2)	113.1 (20.6)
Body Mass Index (kg/m^2) Mean (SD)	39.7 (6.4)	44.4 (3.7)	42.0 (5.7)
Type II Diabetes Mellitus n (% of Cohort)	1 (4.0%)	9 (37.5%)	10 (20.4%)

Safety Definitions

Adverse events were categorized according to the Clavien-Dindo Classification grading system, a standard scale for ranking surgical complications based on deviation from a normal post-operative course, severity, and level of intervention required. Grades are defined as:

- Grade I: Deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Antiemetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy allowed.
- Grade II: Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition included.
- Grade III: Requiring surgical, endoscopic, or radiological intervention.
- Grade IV: Life-threatening complication (including certain CNS complications) requiring Intermediate Care/Intensive Care Unit-management.
- Grade V: Death of a patient.

Relationship to the study device (Magnet) and/or Study Procedure (including use of the Delivery System or Laparoscopic Positioning Device) was classified as possible, probable, definite, or indeterminate. Events assessed as probable or definite are categorized as Related for causality in this report. Classification definitions are listed below:

- Possible: The relationship with the use of the investigational device or the procedures is weak but cannot be ruled out completely. Alternative causes are also possible (e.g., an underlying or concurrent illness/clinical condition or/and an effect of another device, drug, or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possible.

- Probable: The relationship with the use of the investigational device or procedures seems relevant and/or the event cannot be reasonably explained by another cause.
- Definite: The AE is associated with the investigational device or procedures beyond a reasonable doubt when:
  a. The event is a known side effect of the product category the device belongs to or of similar devices and procedures.
  b. The event has a temporal relationship with investigational device use/application or procedures.
  c. The event involves a body-site or organ that the investigational device or procedures are applied to, or the investigational device or procedures have an effect on.
  d. The AE follows a known response pattern to the medical device (if the response pattern is previously known).
  e. The discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroductions of its use (or increase of the level of activation/exposure), impact on the AE (when clinically feasible).
  f. Other possible causes (e.g., an underlying or concurrent illness/clinical condition or/and an effect of another device, drug, or treatment) have been adequately ruled out.
  g. Harm to the subject is due to error in use.
  h. The event depends on a false result given by the investigational device used for diagnosis, when applicable.
- Indeterminate: Information gathered about the AE is not sufficient to arrive at a definite conclusion about causal relationship.

A Serious adverse event (SAE) was defined according to the definition in ISO 14155:2020 (e.g., event resulting in death, a life-threatening illness or injury, permanent impairment of a body structure or a body function, inpatient hospitalization, or prolongation of existing hospitalization).

Study Procedure

A side-to-side compression anastomosis with the MagDI System (study procedure) was performed for all 49 subjects to establish a duodeno-ileostomy for partial intestinal diversion. Under general anesthesia, two (2) Magnets were sequentially placed using the Delivery System through a flexible endoscope; the first (distal) Magnet was placed at the ligament of Treitz, and the second (proximal) Magnet into the proximal duodenum.

Laparoscopic Positioning Devices and standard laparoscopic instruments were used to move the distal Magnet from the ligament of Treitz to the intended position in the ileum, 250 cm from the ileocecal valve, and manipulate the proximal Magnet to the correct position in the duodenum. This specific measurement for the anastomosis was based on the clinical literature and standardized to control for the underlying duodeno-ileal diversion procedure in which a side-to-side anastomosis is indicated in the small bowel. Laparoscopic instruments were used to lift the ileum loop with intraluminal distal Magnet to meet the proximal Magnet in the duodenum enabling the Magnets to connect (or dock) via polar attraction of the devices through the intestinal walls. The study protocol also included closure of the mesentery defect to standardize the surgical procedure and mitigate potential risk of internal hernia and intestinal obstruction,

known risks for laparoscopic and open abdominal surgeries.

Safety and Effectiveness Results

Primary Effectiveness Endpoint:
The MagDI System was successfully placed in all 49 (100%) attempted study procedures with alignment (docking of the Magnets together). In one case, placement required an enterotomy due to intestinal malrotation, and Magnets were placed successfully. No adverse events were reported related to this placement. The protocol included instructions for such placement as risk mitigation.

Creation of a patent anastomosis was confirmed radiographically in 100% of the subjects. The device passed successfully in natural bowel movements for all (100%, 49/49) subjects, and none (0%) required invasive re-intervention.

The MagDI System successfully met feasibility/performance criteria pre-defined in the protocol for all (100%, 49/49) subjects as shown in Table 15.

Table 15. Feasibility/Performance Criteria

Protocol Feasibility/Performance Criteria	n (%)
Placement of the device with ≥90% alignment of Magnets	49 (100%)
Passage of the device without invasive re-intervention	49 (100%)
Creation of a patent anastomosis confirmed radiologically	49 (100%)

The median hospital stay post procedure was 2 days (n=49; mean 3.5 days (SD 6.4 days)) for all subjects. The post-procedure stay was shorter for those subjects receiving the study procedure only, with a median of 1 day (n=25; mean 1 day (SD 0.3 days)) compared to the cohort receiving the study procedure plus a concurrent non-study sleeve gastrectomy with a median of 3.5 days (n=24; mean 6 days (SD 8.4 days)).

The time to device expulsion (days from study procedure to passage of the device (naturally in bowel movements) in all subjects ranged from 14 to 93 days with a median of 41 days (n=49; mean 46.7 days (SD 23.1 days). Subjects were trained to examine their stools for passage of the device and report the date of expulsion to the study investigator. Two of the subjects indicated they did not know the device had passed as they did not feel it, but passage was confirmed through imaging. Imaging to confirm passage of the device was conducted for all to ensure no Magnets remained in any subject.

The devices retrieved from the first-in-human cases after passing were visually inspected for signs of damage and photos taken of each device. The expelled devices had indications of usage, such as minor scratches and discoloration of the metal, but were generally in good condition. One (1) Magnet had visual evidence of approximately 2mm of the nitinol core wire sticking through the polyester fibers of the suture loop. The wire did not extend beyond the edge of the outer titanium housing. The subject passed this Magnet naturally and reported no adverse events (e.g., abrasions, bleeding, pain), indicating that no tissue was damaged in the subject. During the

clinical study, the subject underwent x-ray examinations per protocol and there were no reports that the wire protruded at that time. The most likely explanation is that the suture was damaged ex vivo during one of the cleaning or shipping processes, which is beyond the life cycle of the device. Based on this information, it appears that the device does not have unintended erosions of the material during its transit through the gastrointestinal tract.

The median expulsion time for the subjects receiving only the study procedure (no concurrent sleeve gastrectomy) was 38 days (n=25; mean 44 days (SD 24.2 days)). For those subjects receiving the study procedure followed by a sleeve gastrectomy (non-study), the median was 51.5 days (n=24; mean 49.7 days (SD 22 days)).

Safety Endpoints:

A total of 89 adverse events were reported in 33 unique subjects, comprising 34 grade I (38.2%), 36 grade II (40.4%), and 19 grade III (21.3%) events on the standard Clavien-Dindo Classification grading system for ranking surgical complications and no events (0%) reaching grades IV or V (life-threating complication or death). Most adverse events (84.2%, 75/89) were reported in subjects receiving the study procedure followed immediately by a sleeve gastrectomy (non-study procedure). Fourteen events (15.7%, 14/89) occurred in subjects receiving only the study procedure. Table 16 presents a summary of adverse events.

Table 16. Adverse Event Summary

Study Time Period (n subjects followed)	MagDI System Procedure Only (n=25)	MagDI System Procedure + SG (n=24)	All Subjects (n=49)
Unique subjects with AEs – (n (% of Cohort))	10 (40.0%)	23 (95.8%)	33 (67.3%)
Total AEs – (n (% of Total AEs))	14 (15.7%)	75 (84.23%)	89 (100%)
AEs Related to the Magnet (n (% of Total AEs))	0 (0%)	0 (0%)	0 (0%)
AEs Related to Procedure* (n (% of Total AEs))	4 (4.5%)	32 (36%)	36 (40.4%)
SAEs – (n (% of Total AEs))	4 (4.5%)	10 (11.2%)	14 (15.7%)

*None were determined related to the Delivery System or Laparoscopic Positioning Devices (MagDI System components)

All AEs are summarized in Table 17 using the Clavien-Dindo Classification grading system for ranking surgical complications based on deviation from a normal postoperative course, severity, and level of interventions required.

Table 17. Adverse Events by Clavien-Dindo Classification Grading by Procedure Cohort

Clavien-Dindo Classification (n subjects)	MagDI System Procedure Only (n=25)	MagDI System Procedure + SG (n=24)	All Subjects (n=49)
Grade I: (n (% of Cohort AEs)) Deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Antiemetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy allowed.	5 (35.7%)	29 (39.7%)	34 (38.2%)
Grade II: (n (% of Cohort AEs)) Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition included.	3 (21.4%)	33 (45.2%)	36 (40.4%)
Grade III: (n (% of Cohort AEs)) Requiring surgical, endoscopic, or radiological intervention.	6 (42.8%)	13 (17.3%)	19 (21.3%)
Grade IV: (n (% of Cohort AEs)) Life-threatening complication (including certain CNS complications) requiring Intermediate Care/Intensive Care Unit-management.	0 (0%)	0 (0%)	0 (0%)
Grade V: (n (% of Cohort AEs)) Death of a patient.	0 (0%)	0 (0%)	0 (0%)
TOTAL Adverse Events in Cohort	**14 (100%)**	**75 (100%)**	**89 (100%)**

Nineteen adverse events (21.3%, 19/89) were grade III Clavien-Dindo, requiring surgical intervention. None were determined related to the Magnets and eleven (12.3%, 11/89) assessed as related to the study procedure. Seven (7) of these were serosal tissue tears observed prior to closing the surgical procedure with none reaching the level of a serious adverse event (SAE). These events were determined related to the use of standard laparoscopic bowel forceps to manipulate the intestines during the grasp (grasping the bowel) and slide (sliding the intraluminal Magnet with the Laparoscopic Positioning Device) maneuver to move the distal Magnet to the desired position in the ileum; all were repaired at the time of the surgical procedure with no additional sequelae. None were attributed to the Laparoscopic Positioning Device. These events were conservatively assigned as grade III given; they may have required surgical intervention to repair if they had not been repaired prior to closing the study procedure. The additional two (2) grade III events included a jejunal intestinal obstruction (at the mesenteric defect despite surgical closure as per protocol) and a pelvic collection, both qualified as SAEs and are further described in Table 18 below.

Seventy-five of all the adverse events (84.2%, 75/89) occurred in the cohort receiving the study procedure plus a concurrent sleeve gastrectomy (non-study procedure) and 95.8% (23/24) of the subjects in this group experienced at least one adverse event. The study procedure only cohort (no concurrent sleeve gastrectomy) had fewer adverse events overall (16.1%, 14/87) and 40% (10/25) experienced an adverse event.

Given the possible challenges in determining device-relatedness for a given adverse event, the Sponsor has identified the following potential risks that may be associated with the use of the subject device:

- Bowel obstruction
- Ileus

- Inability to maneuver or couple magnets
- Inability to retrieve magnets
- Inability to disconnect catheter from magnet and/or fracture of connecting elements
- Inability to visualize anatomical structures by endoscopy/laparoscopy
- Migration of the magnets
- Decoupling of the magnets
- Anastomotic leak
- Bleeding
- Peri-operative infection
- Laceration/perforation of the GI tract
- Scarring
- Stenosis
- Need for extended or additional surgery, including enterotomy
- Ulceration
- Abdominal distension
- Abdominal pain
- Internal hernia
- Constipation
- Nausea
- Vomiting
- Tissue damage
- Adverse tissue reaction
- Foreign body response
- Potential for hospitalization
- Potential for death

Serious Adverse Events

Fourteen of all adverse events (15.7% 14/89) met criteria to be reported as a serious adverse event (SAE) as defined by the protocol (i.e., death, life-threatening, permanent impairment, inpatient hospitalization, or prolongation of hospitalization).

None of the SAEs were determined related to the MagDI System components (Magnets, Delivery System, Laparoscopic Positioning Device). Four SAEs (4.5%, 4/89) were determined to be related to the study procedure. One event was a jejunal obstruction due to an internal hernia in the mesentery, despite the closure of the mesenteric defect by the investigator as per study protocol. Laparoscopic repair was performed, and the subject was discharged the following day without sequelae. The second event was a case of pelvic fluid collection of unknown etiology that continued for two months. The subject recovered in good general condition following two transvaginal drainage procedures. The third and fourth together presented in a single subject as a clinically asymptomatic anastomotic stricture identified at endoscopy at the 6 month follow up. Endoscopic balloon dilatation was performed that resulted in an iatrogenic perforation. This was treated with surgical closure of the duodeno-ileal anastomosis, and the subject recovered without further sequelae.

There were no reports of bleeding, leakage, or infection at the anastomosis site and no deaths. All SAEs are presented in Table 18 by relatedness (adjudicated as definitely or probably related to Magnet/ study procedure) and Clavien-Dindo Classification grade.

Table 18. Serious Adverse Events by Relatedness, Severity, and Clavien-Dindo Grade

Adverse Event/Diagnosis/Syndrome	Definitely/Probably Related to Device (Y/N)	Definitely/Probably Related to Procedure (Y/N)	Clavien-Dindo Grade	Percentage of total subjects
Jejunal intestinal obstruction	**N**	**Y**	**III**	**2% (1/49)**
Stricture	**N**	**Y**	**III**	**2% (1/49)**
Iatrogenic perforation from endoscopic stricture balloon dilatation	**N**	**Y**	**III**	**2% (1/49)**
Pelvic Collection	**N**	**Y**	**III**	**2% (1/49)**
Anorexia with diarrhea, nausea and vomiting	**N**	**N**	**II**	**2% (1/49)**
Dehydration	**N**	**N**	**II**	**2% (1/49)**
Kidney Stones	**N**	**N**	**III**	**2% (1/49)**
Cholecystitis	**N**	**N**	**III**	**4% (2/49)**
Cholecystitis with choledocholithiasis	**N**	**N**	**III**	**2% (1/49)**
Menorrhagia with anemia	**N**	**N**	**II**	**2% (1/49)**
Major pneumoperitoneum on gastric fistula	**N**	**N**	**III**	**2% (1/49)**
Abdominal pain and nausea and vomiting	**N**	**N**	**III**	**2% (1/49)**
Peri-anal abscess, gangrene	**N**	**N**	**III**	**2% (1/49)**

The MagDI System performed safely and as intended to create patent side-to-side duodeno-ileal anastomoses in 100% of 49 subjects. There were no reports (0%) of anastomotic bleeding, leakage,

or infection, and no mortality. These clinical data, with over half of the subjects followed to one year, demonstrates an adverse event profile as safe as conventional anastomosis techniques with no reports of the most common anastomotic risks seen with enterotomy and sutures or staples.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population. The MagDI System is indicated for adult patients > 21 years, that is, in adults on, or after their 22nd birthday.

POSTMARKET SURVEILLANCE

There is uncertainty regarding the generalizability of effectiveness of device use in the target U.S. patient population and regarding the incidence and severity of internal hernia. In order to satisfy special control (1) above FDA has determined a postmarket surveillance study is needed to provide additional information on the risk of internal hernia and bowel obstruction. There is uncertainty regarding this specific risk due to the study size consisting of 49 subjects, which may be insufficient to adequately characterize the risk's incidence and severity. Additionally, since the premarket clinical data involved primarily Caucasian, female subjects, there is uncertainty if the device can function as intended in the target U.S. patient population. Therefore, postmarket clinical data is necessary to collect information from demographic groups that had limited representation in the premarket study.

The postmarket study will assess and characterize incidence and severity of internal hernia and bowel obstruction in U.S. patients representative of the U.S. intended use population who are treated with the MagDI System for duodenal-ileal side-to-side anastomosis. The study will be conducted through an observational patient registry at U.S. centers and should include patients from demographic groups representative of the U.S. intended use population who had limited representation in the premarket study (e.g., African American, Asian) and have comorbidities similar to the intended use U.S. population. The study population will consist of U.S. patients, adults over the age of 21, who are willing to provide informed consent, indicated for a side-to-side duodenal-ileal anastomosis, treated with the MagDI System, and with a BMI between 30-50 kg/m^2. The sample size will include all consenting patients, who meet all inclusion and exclusion criteria at selected sites. Subjects will be enrolled within one year after the first enrollment, or until a clinically justified sample size to assess the primary endpoint has been reached. Data collection will be managed using an open-source electronic data system.

The primary endpoint will be the incidence and severity of internal hernia and small bowel obstruction at one year post-side-to-side duodeno-ileal anastomosis created with the MagDI System. Patients will be followed up for at least one year post-index procedure with additional follow up time-points as clinically indicated. The analysis will compare the incidence and severity of internal hernia and bowel obstruction to an appropriately justified comparator group.

LABELING

The labeling for the device is sufficient and satisfies the requirements of 21 CFR 801.109. The labeling consists of package labels and Instructions for Use (IFU). The labeling includes that the

device is intended for single use only, for sale only on order of a physician (Rx only) and is MR unsafe.

The IFU provides a description of the device, indications for use, directions for use, storage conditions, and known and probable risks. The labeling includes appropriate warnings, precautions, contraindications, and limitations of safety information including within the Instructions for Use : "*The MagDI™ System is an anastomotic surgical tool. The device has not demonstrated clinical effectiveness for weight loss or other underlying clinical procedures where a side-to-side duodeno-ileal anastomosis is indicated. The effects of this device on weight loss were not studied.*"

RISKS TO HEALTH

Table 19 below identified the risks to health that may be associated with use of a magnetic compression anastomosis system.

Table 19: Risks to Health and Mitigation Measures

Risks to Health	Mitigation Measures
Inaccurate device placement leading to unsuccessful anastomosis creation	Clinical performance testing Postmarket surveillance Animal performance testing Non-clinical performance testing Labeling
Anastomotic leaking, bleeding from device decoupling	Clinical performance testing Postmarket surveillance Non-clinical performance testing Labeling
Obstruction from • Internal hernia • Device expulsion failure • Anastomotic stricture/stenosis	Clinical performance testing Postmarket surveillance Labeling
Infection/sepsis	Clinical performance testing Postmarket surveillance Sterilization validation Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Tissue damage (e.g., laceration, serosal tear, inflammation, irritation)	Clinical performance testing Postmarket surveillance Animal performance testing Labeling
Intestinal ulceration and/or scarring from device migration	Clinical performance testing Postmarket surveillance Animal performance testing Labeling

Gastrointestinal symptoms (e.g., abdominal distention, diarrhea, constipation, nausea, vomiting)	Clinical performance testing Postmarket surveillance Animal performance testing Labeling
Interference with ferromagnetic implants, devices, or objects	Non-clinical performance testing

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the magnetic compression anastomosis system is subject to the following special controls:

(1) Premarket clinical performance testing and postmarket surveillance must demonstrate that the device performs as intended under anticipated conditions of use in the intended patient population unless FDA determines based on the totality of the information provided for premarket review that data from postmarket surveillance is not required. Testing must:
   (i) Demonstrate the ability to deliver the device to the target anatomic location and rate of successful anastomosis creation;
   (ii) Evaluate all adverse events, including anastomotic leaking, bleeding, obstruction, infection/sepsis, pain, tissue damage, intestinal ulceration and/or scarring, and gastrointestinal symptoms; and
   (iii) Assess rate of successful device passage from the gastrointestinal tract.

(2) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must demonstrate the ability of the device to create an anastomosis supported by histology of the anastomosis site.

(3) Non-clinical performance data must demonstrate that the system performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   (i) Magnetic field strength testing to characterize safe distances from the magnets for patients and users with ferromagnetic implants, devices, or objects; and
   (ii) Ability of the magnetic components to maintain adequate separation forces.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility of any sterile components and continued device functionality over the labeled shelf life.

(7) Labeling must include:

(i) A detailed summary of clinical performance testing conducted with the device, including study population, results, adverse events, and comparisons to any comparator groups identified;
(ii) Magnetic resonance compatibility information;
(iii) An expiration date or shelf life; and
(iv) A detailed summary of any post-market surveillance data collected and any necessary modifications to the labeling to accurately reflect outcomes based upon the postmarket data collected.

BENEFIT-RISK DETERMINATION

BENEFITS

The MagDI System is a compression anastomosis device using magnetic technology to achieve mechanical compression of two device housings. The device successfully created duodeno-ileal side-to-side anastomoses in 49/49 patients in the clinical study, which supports the effectiveness of an anastomotic tool claim. The clinical and animal data showed successful device placement through traditional minimally invasive techniques and instruments, supporting the probable benefit of functioning as an anastomotic tool. The in vivo verification data demonstrates that both magnet components may be positioned and docked together through intraluminal navigation or through an enterotomy. This data supports the probable benefit of flexible placement workflows. Finally, once wound strength is sufficient to maintain the anastomosis, both magnet components are expelled through the normal gastrointestinal pathway. This eliminates the need for device materials to remain in situ. In contrast to other anastomotic devices, such as sutures and staple devices, the subject device has the probable benefit of no long-term foreign body materials residing in the patient, which mitigates the risk of adverse and inflammatory tissue reactions that occur as the result of foreign body reactions.

The clinical study of 49 subjects consisted of largely Caucasian, obese, and female subjects and may not be adequately representative of the normal U.S. demographic make-up in terms of minority representation. Therefore, there is uncertainty if the premarket data is representative of the intended U.S. patient population. Additional postmarket clinical data collection may mitigate these concerns contributing to uncertainty of benefit, and benefit generalizability for this device type.

Risks

1. Stricture: 1/49 study subject was identified with an asymptomatic anastomotic stricture. Strictures are a known risk with anastomotic tools and devices. Adequate labeling informs physicians and patients of this risk, providing a mitigation for this risk.

2. Bowel obstruction and internal hernia: 1/49 study subject experienced an internal hernia resulting in a bowel obstruction, despite closure of the mesenteric defect. Due to the small clinical study size, it is unclear what the rate and severity are of the risk of internal hernia leading to bowel obstruction, leading to moderate uncertainty for this risk. Additional postmarket clinical data collection may reduce uncertainty of this risk.

3. Bowel injury: The study noted that bowel injuries (serosal tears) occurred during the intra-luminal navigation of the magnet components into position due to manipulation of the tissue with laparoscopic graspers. The device or components were not directly involved with the injury.

4. Risks from concomitant procedure: Several AEs and SAEs were noted in the cohort receiving both a device anastomosis and concomitant sleeve gastrectomy. The AEs and SAEs associated with the gastrectomy procedure were not related to the subject device.

5. Risk of magnet technology, including dislodgement and effects on tissues/extraneous devices: Adequate bench testing has demonstrated appropriate magnet strength confirmed with animal and clinical testing, despite differences in tissue thickness. Additional contraindications are included to mitigate device-device interactions and to denote MRI-Unsafe. These risks have been adequately mitigated.

6. Risk of patient harm from infection: Low Risk and low uncertainty. Adequate sterility testing has be done to ensure sterility of the final finished product. Adequate sterility and reprocessing instructions are included for the device accessories. Additionally labeling is included to further mitigate this risk. This risk has been adequately mitigated.

7. Risk of patient harm from tissue interactions: Low Risk and low uncertainty. Adequate biocompatibility testing has demonstrated no unintended tissue effects or interactions from any of the device components. This risk has been adequately mitigated.

In summary, the premarket data demonstrates several probable benefits and risks when used in the creation of duodeno-ileal anastomoses. The risks of the MagDI System and clinical study limitations are mitigated by the special controls and labeling. However, since there is uncertainty regarding the generalizability of effectiveness of device use in the target U.S. patient population and since there is uncertainty regarding the incidence and severity of internal hernia; postmarket data collection will be necessary. With the addition of postmarket data collection mitigating the uncertainties related to the premarket clinical data, the benefits outweigh the risks.

References:

1. Kaidar-Person O, Rosenthal RJ, Wexner SD, et al. Compression Anastomosis: History and Clinical Considerations. The American Journal of Surgery. 2008; 195: 818-826. https://www.doi.org/10.1016/j.amjsurg.2007.10.006.
2. Tabola R, Cirocchi R, Fingerhut A, et al. A Systematic Analysis of Controlled Clinical Trials Using the NiTi CAR™ Compression Ring in Colorectal Anastomoses. Tech Coloproctol. 2017; 21(3): 177-184. https://www.doi.org/10.1007/s10151-017-1583-2.
3. Buchberg BS, Masoomi H, Bergman H, et al. The Use of a Compression Device as an Alternative to Hand-Sewn and Stapled Colorectal Anastomoses: Is Three a Crowd? Journal of Gastrointestinal Surgery. 2011; 15:304-310. https://www.doi.org/10.1007/s11605-010-1376-7.

Patient Perspectives
This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion
In conclusion, given the available information above, for the following indication statement:

> The GT Metabolic MagDI System is intended for use in the creation of side-to-side duodeno-ileal anastomoses in minimally invasive and laparoscopic surgery. Once wound strength is sufficient to maintain the anastomosis, the device is passed from the body. The effects of this device on weight loss were not studied.
>
> The GT Metabolic MagDI System is intended for use in adult patients > 21 years.

The probable benefits outweigh the probable risks for the MagDI 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 MagDI™ System is granted, and the device is classified as follows:

Product Code: SAH
Device Type: Magnetic compression anastomosis system
Class: II
Regulation: 21 CFR 878.4816