July 2, 2024

GT Metabolic Solutions, Inc.
Lisa Griffin Vincent
Chief Regulatory/Quality Officer and General Manager
3050 Three Springs Court
San Jose, California 95140

Re: DEN240013
Trade/Device Name: MagDI System
Regulation Number: 21 CFR 878.4816
Regulation Name: Magnetic compression anastomosis system
Regulatory Class: Class II
Product Code: SAH
Dated: March 25, 2024
Received: March 26, 2024

Dear Lisa Griffin Vincent:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the MagDI System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the MagDI System, and substantially equivalent devices of this generic type, into Class II under the generic name magnetic compression anastomosis system.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on March 18, 2024 automatically classifying the MagDI System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II.

On March 26, 2024, FDA received your De Novo requesting classification of the MagDI System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the MagDI System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request and information submitted interactively, FDA has determined that, for the previously stated indications for use, the MagDI System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

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.

In order to satisfy special control (1) above, FDA has determined that you must conduct one postmarket surveillance study as outlined below.

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 sponsor will provide a statistical analysis plan with their postmarket study protocol.

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 clinicially indicated. The analysis will compare the incidence and severity of internal hernia and bowel obstruction to an appropriately justified comparator group.

Within 30 days of receipt of this order, you must submit a complete study protocol for your study as described above. FDA expects to work with you to approve your study protocol within 60 days of this order. Your submission should be clearly labeled as a "De Novo Postmarket Study Protocol" and submitted to the Agency as specified below. Please reference the De Novo number above to facilitate processing. If there are multiple protocols being finalized after granting of this De Novo request, please submit each protocol as a separate submission, identified by their unique study name(s).

From the date of postmarket study protocol approval, you must meet the following timelines:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months

In addition, you must submit separate periodic reports on the progress of the new enrollment postmarket study as follows:

- Postmarket surveillance progress reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the protocol approval letter, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports every three (3) months in addition to your periodic postmarket surveillance progress reports, until enrollment has been completed or FDA notifies you otherwise.
- Submit the final postmarket surveillance report three (3) months from study completion (i.e., last subject's last follow-up date).

Each postmarket surveillance report should be submitted to the Agency as specified below, identified as a "De Novo Postmarket Surveillance Report" in accordance with how the study is identified above, and bearing the applicable De Novo reference number.

Be advised that failure to comply with any special control requirement, including the initiation, enrollment, completion, and reporting per the postmarket surveillance data requirements outlined above, may result in the adulteration and misbranding of your device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the magnetic compression anastomosis system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above De Novo number to facilitate processing.

De Novo Postmarket Surveillance
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Alternatively, documents can be submitted electronically through the CDRH Portal. For more information on the CDRH Portal, please visit https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

If you have any questions concerning the contents of the letter, please contact Tajanay R. Ki at 301-796-6441.

Sincerely,

Barton Sachs -S
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for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health