February 28, 2025

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

Re: K243359
Trade/Device Name: MagDI System (MAG-02, DS-01)
Regulation Number: 21 CFR 878.4816
Regulation Name: Magnetic Compression Anastomosis System
Regulatory Class: Class II
Product Code: SAH
Dated: January 27, 2025
Received: January 27, 2025

Dear Lisa Griffin Vincent:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2025.02.28 14:16:57 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243359

Device Name

MagDI System (MAG-02, DS-01)

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
(K243359)

Submitter:

GT Metabolic Solutions, Inc.
3050 Three Springs Court, San Jose, CA 95140
Phone: 612-222-4200

Contact Person: Lisa Griffin Vincent, PhD, MA
Date Prepared: February 28, 2025

Name of Device:

Proprietary/Trade Name:	GT Metabolic MagDI™ System
Device Common Name:	Magnet System
Model Numbers:	MAG-02 DS-01
Product Code Name:	Magnetic compression anastomosis system
Product Code:	SAH
Regulation Number:	878.4816
Review Panel:	General & Plastic Surgery
Device Classification:	Class II

Predicate Device:

Proprietary/Trade Name:	GT Metabolic MagDI™ System
Device Common Name:	Magnet System
Model Numbers:	MAG-01 DS-01
Submission Number:	K242086
Product Code Name:	Magnetic compression anastomosis system
Product Code:	SAH
Regulation Number:	878.4816
Review Panel:	General & Plastic Surgery
Device Classification:	Class II

Reference Device:

Proprietary/Trade Name:	GT Metabolic MagDI™ System
Submission Number(s):	DEN240013

Product Code Name:	Staple, implantable
Product Code:	Magnetic compression anastomosis system
Regulation Number:	SAH
Review Panel:	878.4816
Device Classification:	Class II

Device Description:
The set of two (2) Magnets is a sterile single-use device. The device provides a simple method for the creation of a round (oval/circular) compression anastomosis.
After a period of 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.

Intended Use / 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.

Technological Characteristics:
The subject device, GT Metabolic MagDI™ System does not change the fundamental magnetic compression anastomosis technology employed in the predicate device and has the same intended use and same Indications for Use. The subject device is changing the device length only (a planned variant to the GT Metabolic DI Magnet) while maintaining similar compression strength. The GT Metabolic MagDI™ System device provides surgeons with the option to choose length of DI Magnet based on medical judgement according to individual patient morphology, clinical characteristics, and underlying clinical procedure.

Performance Testing:
Preclinical Testing

- Biocompatibility testing demonstrated the device is biocompatible according to ISO 10993-1.
- Magnet field strength testing characterized the distances from the magnets are safe for patients and users with ferromagnetic implants, devices, or objects.
- The Magnets maintain adequate separation forces over the use life.
- The Magnets connect and disconnect to the Delivery System over the use life.

- Patient-contacting materials conform to ISO 10993-1 and FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* issued September 8, 2023.
- The MagDI System demonstrates a SAL of 10^{-6}, a continued sterility through the labeled shelf life of the device, and conforms to ISO 11137-1, ISO 11137-2, and ISO 11137-3.

Animal and Clinical Testing

- Animal testing was not required for this submission based on risk analysis. The sole change to the predicate device is length of the GT Metabolic DI Magnet. The change does not raise any new questions of safety or effectiveness for the same intended use and Indications for Use.
- Clinical testing was conducted in obese patients with or without type 2 diabetes mellitus using the MagDI System for creation of a side-to-side duodeno-ileal anastomosis. The Magnets were sequentially delivered orogastrically either by swallow or endoscopically using the Delivery System. The Magnets were successfully placed in all cases with alignment and created patent anastomoses confirmed by imaging. The device was expelled naturally in most of the subjects reaching the one-month study visit. In one case, the device was removed via colonoscopy without issues after creating a patent anastomosis and naturally progressing through the small bowel with no issues or signs of blockage or bowel abnormalities. This subject was assessed as having low bowel motility. Most adverse events were of low grade, Clavien-Dindo Classification I-II and only one serious adverse event (SAE). No cases of internal hernia or bowel obstruction were reported. There were no cases of anastomotic bleeding, leakage, infection, or obstruction and no deaths. The MagDI System (K243359) performed safely and as intended to create patent duodeno-ileal side-to-side anastomoses with a profile as least as safe as the predicate compression anastomosis device (MagDI System, K242086).
- The subject device will be subject to and incorporated into the same post-market surveillance study as the predicate device (K242086) to 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.

Labeling conforms to 21 CFR 801 and ISO 15223.

Substantial Equivalence Conclusion:

The proposed subject device, GT Metabolic Solutions MagDI™ System (MAG-02 (50mm), DS-01), is a modification and planned variant to the predicate MagDI System (MAG-01 (39mm), DS-02; K242086). The subject device has demonstrated to be substantially equivalent to the predicate device (K242086) based on the same intended use and same Indications for Use, same or similar technological characteristics, and on performance testing.