June 04, 2026

GT Metabolic Solutions, Inc.
Lisa Griffin Vincent
Chief Regulatory, Quality, Clinical Officer
5450 Quam Avenue N.E.
Suite 100
St. Michael, Minnesota 55376

Re: K253102
Trade/Device Name: GT Metabolic MagDI System (MAG-01, MAG-02, DS-01)
Regulation Number: 21 CFR 878.4816
Regulation Name: Magnetic Compression Anastomosis System
Regulatory Class: Class II
Product Code: SAH
Dated: April 29, 2026
Received: April 30, 2026

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.

Per the July 2, 2024 De Novo classification order for this device type, you must demonstrate that the device performs as intended under anticipated conditions of use in the intended patient population. The special

control requirements set forth in that order include initiation, enrollment, completion, and reporting requirements associated with any required postmarket surveillance. Within 30 days of receipt of this letter, you must submit a complete study protocol for a postmarket surveillance study consistent with the special control requirements. FDA expects to work with you to approve your study protocol within 60 days of this letter. Your submission should be clearly labeled as a "Postmarket Study Protocol" and submitted to the Agency as specified below. Please reference the 510(k) number above to facilitate processing. If there are multiple protocols being finalized after clearance of this 510(k) submission, please submit each protocol as a separate submission, identified by their unique study name(s).

From the date of 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 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 enrollment status reports every three (3) months in addition to your periodic postmarket study progress reports, until enrollment has been completed, or FDA notifies you otherwise.
- Submit the final postmarket study 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 "Postmarket Surveillance Report" in accordance with how the study is identified above, and bearing the applicable 510(k) 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.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production

(ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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).

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above 510(k) number to facilitate processing.

Postmarket Mandated Studies Programs
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.

Sincerely,

TEK N. LAMICHHANE
-S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and 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.

510(k) Number *(if known)*
K253102

Device Name
GT Metabolic MagDI™ System

Indications for Use *(Describe)*
The GT Metabolic MagDI System (MAG-01, MAG-02, DS-01) is intended for use in the creation of side-to-side anastomoses throughout the small bowel 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 MagDITM 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.

510(k) Summary
(K253102)

Submitter:
GT Metabolic Solutions, Inc.
5450 Quam Avenue NE, Suite 100, St. Michael, MN 55376
Phone: 612-222-4200

Contact Person: Lisa Griffin Vincent, PhD, MA
Date Prepared: June 3, 2026

Name of Device:

Proprietary/Trade Name:	GT Metabolic MagDI™ System
Device Common Name:	Magnet System
Model Numbers:	MAG-01, MAG-02 DS-01
Product Code Name:	Magnetic compression anastomosis system
Product Code:	SAH
Associated Product Code:	GAD
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, MAG-02 DS-01
Submission Number(s):	K242086, K243359
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:	Flexagon Plus OTOLoc System
Common Name:	Self-Forming Magnet System
Submission Number(s):	K250541

Product Code Name:	Magnetic compression anastomosis system
Product Code:	SAH
Regulation Number:	878.4816
Review Panel:	General & Plastic Surgery
Device Classification:	Class II

Device Description:

The set of two (2) Magnets (either a set of 40mm (MAG-01) or 50mm (MAG-02) 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 (MAG-01, MAG-02, DS-01) is intended for use in the creation of side-to-side anastomoses throughout the small bowel 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 is the same device (i.e., all technological characteristics remain the same) as the predicate GT Metabolic MagDI™ System (K242086, K243359) and has the same intended use for side-to-side anastomosis in the small bowel. The submission is expanding Indications for Use from “duodeno-ileal anastomosis” to “anastomosis throughout the small bowel” based on the clinical testing provided.

Performance Testing:

Preclinical.and.Animal.Testing

- Preclinical testing was not required for this submission based on risk analysis. There were no technological changes to the subject device from the predicate device (K242086, K243359), and the intended use remains the same.
- Animal testing was not required for this submission based on risk analysis.

Clinical.Testing

- The MagDI System (using the longest 50mm Magnet) for creation of side-to-side jejuno-ileal anastomosis was clinically tested in patients with obesity and type 2 diabetes mellitus. The performance endpoint at 90 days was met with successful placement, creation of patent anastomoses, and natural elimination of the set of connected Magnets in all cases (100%, 9/9). Most adverse events were of a low

grade Clavien-Dindo I-II (86.4%, 19/22) with no events (0%) related to the Magnet device. There was only one SAE, not assessed as related to the device or study procedure, a glioma presenting with an epileptic seizure and leading to excision. The MagDI System performed safely and as intended to create patent magnetic compression anastomosis in the small bowel with no cases of anastomosis leakage, obstruction, or infection, and no mortality with all subjects followed to one year for study completion.

- Additional data was analyzed, including real-world clinical practice use of the MagDI System (40mm and 50mm Magnets) for small bowel anastomosis at the medical discretion of the treating physician (n=26 cases); jejuno-ileostomy, duodeno-jejunostomy, jejuno-jejunostomy, and gastric remnant-jejunostomy. Applications included use in Superior mesenteric artery syndrome (SMAS); limb lengthening following severe malnutrition after Biliopancreatic diversion (BPD); revision of Roux-en-Y gastric bypass (RYGB); and reversal of a Duodenal Switch procedure due to chronic diarrhea and malnutrition. The MagDI System performed safely and as intended for small bowel anastomosis in all cases (100%) with no reports of SAEs related to the device or procedure.
- The subject device will be subject to and incorporated into the same ongoing post-market surveillance study as the predicate device (K242086, K243359) 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 side-to-side anastomosis throughout the small bowel.

Labeling conforms to 21 CFR 801 and ISO 15223.

Substantial Equivalence Conclusion:

The proposed subject device, GT Metabolic MagDI™ System (MAG-01 (40mm), MAG-02 (50mm), DS-01), presents a modification to the Indications for Use with no technological changes and the same intended use as the predicate MagDI System (K242086 (MAG-01, DS-01); K243359 (MAG-02, DS-01)). The subject device has demonstrated to be substantially equivalent to the predicate device based on the same intended use and same technological characteristics, with clinical performance testing supporting an expanded Indications for Use to side-to-side anastomoses throughout the small bowel.