August 04, 2025

GI Windows Inc.
Yverre Bobay
Regulatory VP
381 University Ave.
Westwood, Massachusetts 02090

Re: K243482
Trade/Device Name: Self-Forming Magnet (Flexagon)
Regulation Number: 21 CFR 878.4816
Regulation Name: Magnetic Compression Anastomosis System
Regulatory Class: Class II
Product Code: SAH

Dear Yverre Bobay:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on June 11, 2025, to correct an administrative omission and describe the postmarket study requirement in alignment with existing special control requirements for this device type.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Tek Lamichhane, Ph.D., OHT4: Office of Surgical and Infection Control Devices, 301-796-8983, Tek.Lamichhane@fda.hhs.gov.

Sincerely,

Alexander Nguyen -S

for 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

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Regulation Number: 21 CFR 878.4816
Regulation Name: Magnetic Compression Anastomosis System
Regulatory Class: Class II
Product Code: SAH
Dated: November 8, 2024
Received: November 8, 2024

Dear Yverre Bobay:

This letter corrects our previous letter, dated June 11, 2025, to correct an administrative omission and describe the postmarket study requirement in alignment with existing special control requirements for this device type.

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, and the July 2, 2024 De Novo classification order for this

type of device. 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 the previous letter dated June 11, 2025 (July 11, 2025), 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 the June 11, 2025 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 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).

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 Program

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,

Alexander Nguyen -S

For: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243482

Device Name
Self-Forming Magnet (FLEXAGON)

Indications for Use *(Describe)*
The GI Windows FLEXAGON 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 GI Windows FLEXAGON 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(K243482)

Contact Details

Applicant Name: GI Windows, Inc.
Applicant Address: 381 University Ave., Westwood, MA 02090
Applicant Contact Telephone: 617 669 6181
Applicant Contact: Ms. Yverre Bobay
Applicant Contact Email: Yverre.bobay@giwindows.com

Device Name

Device Trade Names: Self-Forming Magnet (FLEXAGON)
Common Name: Self-Forming Magnet
Classification Name: Magnetic Compression Anastomosis System
Regulation Number: 878.4816
Product Codes: SAH

Legally Marketed Predicate: FLEX SFM (243213) - Product Code: SAH

Legally Marketed Reference: Mag DI (DEN240013) – Product Code: SAH

Limitations

The sale, distribution, and use of the Flexagon 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 Summary

The FLEXAGON device is a magnetic compression anastomosis system, which is a surgical device used for the creation of anastomoses in minimally invasive surgery in the gastrointestinal tract. The system is comprised of magnets and includes the delivery systems. Compression and necrosis of tissue between magnet devices is created by polar attraction of the magnet devices with subsequent healing of tissue around the devices. Once the anastomosis is formed the magnet device is expelled naturally in approximately 3-6 weeks.

Figure 1 – Flexagon Self-Forming Magnet

Intended Use/Indications for Use:

The GI Windows FLEXAGON 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 GI Windows FLEXAGON is intended for use in adult patients > 21 years.

Indications for Use Comparison:

There is no change to Indications for Use in comparison to the predicate device.

Technological Comparison

The FLEXAGON and predicate device systems have the same technological characteristics (principal of operation, magnetic core technology, anatomical target placement location and packaging) as the predicate devices as shown in **Table 1**.

Table 1 - FLEXAGON Comparison with Predicate and Reference Devices

Characteristics	FLEXAGON SFM Proposed – K243482	FLEX SFM Predicate - K243213
Core Technology Method	Magnetic compression	Same
Technological Characteristics (Magnets)	When the two magnets are positioned to be in close proximity with each other, the magnets are attracted to one another. Visually it can be confirmed by physicians when the magnets are properly coupled together, thereby starting the formation of a compression anastomosis.	Same
Mechanism of Action	The clamping pressure provided by the magnets is sufficient to cause tissue hypoxia to occur in the tissue microenvironment during healing of the anastomotic site[1]. Necrosis of the trapped tissue then occurs around and between the assemblies. As the surrounding tissue heals and the coupled magnets fall away, the desired anastomosis is formed. The coupled magnets naturally pass through the intestinal tract.	Same

[1] Wang et al., Magnamosis improves the healing of gastrojejunal anastomosis; Nature (2024) 14:20367 | https://doi.org/10.1038/s41598-024-71215-7

Characteristics	FLEXAGON SFM Proposed – K243482	FLEX SFM Predicate - K243213
Magnet Implant Dimensions	In the octagonal shape, the Outer diameter is 25 mm X Inner diameter is 18 mm X 3 mm Thickness	Same as Flexagon
Overall length Flat-to-Flat Dimension	25.5 mm	25.8 mm
Magnet Materials	• Neodymium-iron-boron (NdFeB) magnet, electroplated with nickel and copper • Stainless steel • Nitinol wire and sheath • Ultra-High Molecular Weight Polyethylene Suture Loctite, Instant Adhesive	• Neodymium-iron-boron (NdFeB) magnet, electroplated with nickel, gold and copper • Stainless steel • Nitinol frame • Polybutester Suture Loctite, Instant Adhesive
SFM Coatings	Parylene C-coated	Same
Minimum Anastomotic Clamping Force at 4mm Specification	≥0.38 lbf	≥0.38 lbf
Minimum Anastomotic Clamping Pressure at 1mm Specification	≥10 PSI	≥10 PSI
Magnetic Interference	Static magnetic field strength ≤10 gauss at 11 mm from the device. The device is also labelled as MRI unsafe.	Static magnetic field strength of predicate is ≤10 gauss at a distance of 10 mm. The device is also labelled as MRI unsafe.
Clinical Anastomosis Formation: **-Clinical placement of the device with ≥90% alignment of magnets** **-Creation of a patent anastomosis confirmed radiologically (day 30)**	all subjects (100%) all subjects (100%)	all subjects (100%) all subjects (100%)

Summary of Performance Data

The determination of substantial equivalence is based on an assessment of non-clinical performance data. To verify that the device design meets the functional and performance requirements, FLEXAGON underwent the following performance testing. The tests were performed on the subject devices using similar method and acceptance criteria as the predicate device.

- Transportation Validation and Shipping test / ASTM D 4169: 2022
- Biocompatibility tests / ISO 10993 standards. The test items include Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Subchronic Toxicity, Genotoxicity and Chemical Characterization, and Toxicological risk assessment to address additional end points
- E-Beam Radiation Sterilization Validation to an SAL of 1 x 10-6 / ISO 11137-1:2006 +A1:2013 and EN ISO 11137-1:2015
- Porcine Survival Studies
- Simulated Use Cadaver testing
- Packaging Validation
- Shelf-life testing
- Device performance tests on magnet clamping force, pressure and magnetic interference and corrosion resistance.
- Simulated use testing of magnet and delivery devices

Biocompatibility/Materials

Biocompatibility for the Flexagon 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 Flexagon System passed per ISO 10993-1.

Biocompatibility as performed on the magnet assembly (Tables 2-3) and delivery devices (Tables 4-5).

Table 2: Magnet Materials, Type and Duration of Contact

Material	Type and Duration of Contact (ISO 10993-1)
• Parylene C, nickel, copper-coated neodymium magnet • Stainless steel • Nitinol • Loctite cyanoacrylate (med grade) • Loctite silicone adhesive (med grade) • Ultra-High Molecular Weight Polyethylene	**Contact Type** Surface Mucosal membrane **Contact Duration** Long Term (>30 days)

Table 3: Biocompatibility Testing Summary for Magnets

Test Performed	Test Method	Results
Cytotoxicity	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: Biological tests for medical devices; tests for irritation.	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 - Bacterial Reverse Mutation; Mouse Lymphoma Assay	ISO 10993-3: Biological Evaluation of Medical Devices Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity	Pass – non-mutagenic
Systemic toxicity/ Implantation	ISO 10993-11: ISO Systemic Toxicity Study in Rats Following Subcutaneous Implantation	Pass – No systemic toxicity
Chemical Characterization and Toxicological Risk Assessment	ISO 10993-18: Biological evaluation of medical devices – Part 18: Chemical characterization of materials and ISO 10993-17, Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances.	Pass - The test articles remained visibly unchanged post-extraction.

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

Material	Type and Duration of Contact (ISO 10993-1)
• Ultem (polyetherimide)Stainless steel • Stainless steel • Titanium Grade 4 • High Density Polyethylene (HDPE) • Ultra-High Molecular Weight Polyethylene • PEEK epoxy adhesive • PEBAX UV curable adhesive • ABS polycarbonate blend • Delrin alloy steel • Polycarbonate cyanoacrylate adhesive	**Contact Type** Surface Mucosal membrane **Contact Duration** Limited (≤24h)

Material	Type and Duration of Contact (ISO 10993-1)
• Thermoplastic polyurethane • Au, NiCuNi plated, parylene coated neodymium	

Table 5: Biocompatibility Testing Summary for Delivery System

Test Performed	Test Method	Results
Cytotoxicity	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: Biological tests for medical devices; tests for irritation.	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

Shelf Life/ Sterility

Shelf-life testing comprised of aging the Flexagon System and then performing the design verification testing. The Flexagon System (Magnet and Delivery System) was validated for sterility via E-beam 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. All testing occurred on units that were pre-conditioned per the requirements of recommended international standards to substantiate distribution and a prescribed shelf life.

Magnetic Resonance (MR) Compatibility

The Flexagon System is MR unsafe.

Software

The Flexagon System does not contain software

GLP Animal Studies

GLP animal studies were conducted to evaluate the FLEXAGON device and accessories for use in the small bowel anastomosis in comparison to a 60mm linear stapled anastomosis as a control in a porcine model.

In all evaluations, the animals were survived to 42+5 days and the magnets were all expelled within 20 days. The FLEXAGON implant, their associated delivery systems and the anastomoses created using the GI Windows products performed as well as or better than the stapled anastomosis in the control subjects and anastomoses when evaluating tissue burst pressure and histological architecture of the healed tissue. The FLEXAGON self-forming magnets as well as the associated delivery devices met all the usability, safety and effectiveness acceptance criteria predefined in the protocols. There were no device failures reported with the magnets or

delivery tools. Compared to a common, standard-of-care, control stapled anastomoses, the GI Windows device is safe, effective and capable of creating a durable small bowel to small bowel anastomosis in a chronic swine anastomosis model.

Cadaver Study
Multiple Cadaver studies were conducted using the Flexagon SFM and delivery devices to perform small bowel anastomosis procedure development for both Single Anastomosis Duodeno-ileal Anastomosis Bypass with Sleeve Gastrectomy (SADI-S) and Duodenal-ileal magnet anastomosis diversion procedures.

In all procedures evaluated in the cadaver studies, the Flexagon SFMs were deployed correctly and the Flexagon SFMs coupled successfully. Surgeons rated the ease of use of the Flexagon SFMs as very easy from their experience creating anastomosis procedures.

FLEXAGON SFM Clinical Data
Clinical testing was conducted (in Chile and India) in patients using the Flexagon System to create side-to-side duodenal-ileal anastomoses. The Magnets were sequentially delivered endoscopically and laparoscopically using the Delivery Systems. The Magnets were successfully placed in all cases with alignment, and for all subjects, the device passed as a pair of connected Magnets naturally or with minimal non-surgical intervention. Most adverse events were of low grade, Clavien-Dindo Classification I-II and those that met the criteria as a serious adverse event (SAE), were resolved without sequelae. There were no cases of anastomotic bleeding, leakage and no deaths. The Flexagon System performed safely and as intended to create patent anastomoses with a profile as least as safe as the predicate compression anastomosis device (FLEX SFM System, K243213).

Postmarket Surveillance
The subject device will be subject to and incorporated into the same postmarket surveillance study as the predicate (K243213) to address outstanding uncertainty regarding the generalizability of effectiveness of the device use in the target U.S. patient population.

Substantial Equivalence Conclusion
Based on the nonclinical and clinical evaluations completed, the Flexagon device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, FLEX SFM (K243213). The subject device, GI Windows Flexagon System has demonstrated to be substantially equivalent to the predicate device, FLEX SFM based on the same intended use and Indications for Use, technological characteristics and performance testing.