January 29, 2025

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

Re: K243213
Trade/Device Name: Self-Forming Magnet (FLEX SFM)
Regulation Number: 21 CFR 878.4816
Regulation Name: Magnetic Compression Anastomosis System
Regulatory Class: Class II
Product Code: SAH
Dated: October 2, 2024
Received: October 3, 2024

Dear Yverre Bobay:

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 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 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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2025.01.29 17:27:27 -05'00'

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)*
K243213

Device Name
FLEX SFM

Indications for Use *(Describe)*
The GI Windows FLEX SFM 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 FLEX SFM 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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510(K) Summary

(K243213)

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 Name: FLEX SFM
Common Name: Self-Forming Magnet
Classification Name: Magnetic Compression Anastomosis System
Regulation Number: 878.4816
Product Codes: SAH

Legally Marketed Predicate: Mag DI (DEN240013) - Product Code: SAH

Device Description Summary

The FLEX SFM device is a magnetic compression anastomosis system, which is a surgical device used for the creation of anastomoses in minimally invasive and laparoscopic surgery in the gastrointestinal tract. The systems are comprised of magnet devices and include delivery systems. 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 (within 3-6 weeks).

Intended Use/Indications for Use:

The GI Windows FLEX SFM 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 FLEX SFM 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 FLEX SFM and predicate device system have the same technological characteristics (principal of operation, magnetic core technology and anatomical target placement location and packaging) as the predicate device as shown in **Table 1**.

Table 1: FLEX SFM Comparison with Predicate		
Characteristics	**FLEX SFM** ***K243213***	**MagDI** ***DEN240013***
Core Technology	Magnetic compression	Same
SFM Electroplating / Coatings	Nickel, Copper, Nickel, Gold, Parylene	Substantially equivalent as proposed and predicate devices are made of biocompatible materials and coatings appropriate for transient implantation in the gastrointestinal system
Magnet Implant Dimensions	In the octagonal shape, the outer diameter is 0.98" (25 mm) X inner diameter is 0.71"(18 mm) X 0.12" (3 mm) thickness	0.75"(19.1mm) length x 0.25" (6.4mm) width x 0.13" (3.2mm) thickness
Overall length Flat-to-Flat Dimension	25.8 mm	19.1 mm length is substantially equivalent in creating an adequately sized duodenal-ileal anastomosis for enteral flow
Magnet placement: target location	Minimally invasive delivery instruments are used to position the magnets to the target anastomosis locations in the duodenum and ileum and connect the two Magnets.	Same
Mechanism of Action	The clamping pressure provided by the magnets is sufficient to cause tissue hypoxia to occur in the 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 magnet assemblies fall away, the desired anastomosis is formed. The	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,

[1] Wang et al., Magnamosis improves the healing of gastrojejunal anastomosis; Nature (2024) 14:20367

Table 1: FLEX SFM Comparison with Predicate		
Characteristics	**FLEX SFM** ***K243213***	**MagDI** ***DEN240013***
	magnets naturally pass through the intestinal tract.	detaches, and is naturally expelled with the stool.[2]
Clinical Anastomosis Formation: **-Clinical placement of the device with ≥90% alignment of magnets**	- N=70 (100%)	- N=49 (100%)[2]
-Creation of a patent anastomosis confirmed radiologically	- N=70 (100%)	-N=49 (100%)[2]
Single Use - Sterile	Self-Forming Magnet (SFM) Anastomosis Device (Magnet A with Endoscopic Delivery Device) and Self-Forming Magnet (SFM) Anastomosis Device (Magnet B with Laparoscopic Delivery Device) are provided sterile and are single use devices	Substantially equivalent as proposed and predicate devices are packaged as sterile devices intended for single use.

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, the FLEX SFM underwent the following performance testing. The tests were performed on the subject device using the same method as the predicate device, and acceptance criteria.

- Transportation Validation and Shipping test / ASTM D 4169: 2022
- Biocompatibility tests / ISO 10993 standards. All patient-contacting components of FLEX SFM system passed per ISO 10993-1. Biocompatibility testing included:
    - Cytotoxicity MEM Elution (ISO 10993-5)
    - Sensitization (ISO 10993-10)
    - Intracutaneous Irritation (ISO 10993-10)
    - Acute Systemic Toxicity (10993-11)
    - Material-Mediated Pyrogenicity (10993-11)

[2] DEN240013 – Mag DI Decision Summary

    - Subchronic Toxicity / Implantation (10993-11 and 10993-6)
    - Genotoxicity – Ames Assay / Mouse Lymphoma Assay (ISO 10993-3)
    - Chemical Characterization (ISO 10993-18)
- 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 tensile strength, magnetic interference and corrosion resistance.

GLP Animal Studies
GLP animal studies were conducted to evaluate the FLEX SFM device for use in the small bowel in comparison to a 60mm linear staple and sutures as controls in a porcine model.

In all evaluations, the FLEX SFM device and the anastomoses created using the GI Windows suite of products performed as well as or better than the control devices and anastomoses when evaluating tissue burst pressure and histological architecture of the healed tissue. The FLEX SFM self-forming magnets met all the usability, safety and effectiveness acceptance criteria predefined in the protocols. There were no device failures reported with the magnets. Compared to a common and accepted control anastomosis devices and procedures, 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.

Clinical
Clinical testing was conducted in patients using the FLEX SFM Device to create side-to-side duodenal-ileal anastomoses in a total of 70 patients, including studies in Argentina, Canada, Spain and the United States. 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 FLEX SFM System performed safely and as intended to create patent anastomoses with a profile as least as safe as the predicate compression anastomosis device (Mag DI System, DEN240013).

Postmarket Surveillance
In summary, the premarket data demonstrates several probable benefits and risks when used in the creation of duodeno-ileal anastomoses. The risks of the FLEX SFM System and clinical study limitations are mitigated by the special controls and labeling. Outstanding uncertainty regarding the generalizability of effectiveness of device use in the target U.S. patient population will be addressed by postmarket data collection associated with special controls requirements. GI Windows will meet defined enrollment milestones following device clearance and will submit periodic postmarket surveillance progress reports until enrollment is complete, followed by annual updates.

Conclusion

Based on the nonclinical and clinical tests completed, the FLEX SFM device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Mag DI (DEN240013). The subject device, GI Windows FLEX SFM System has demonstrated to be substantially equivalent to the predicate device, Mag DI (DEN240013) based on the same intended use and Indications for Use, technological characteristics and performance testing.