October 28, 2026

GI Windows Surgical
Yverre Bobay
VP, Regulatory Affairs
480 Neponset St.
Suite 11-B1
Canton, Massachusetts 02021

Re: K261630
Trade/Device Name: GI Windows Flexagon Plus OTOLoc System
Regulation Number: 21 CFR 878.4816
Regulation Name: Magnetic Compression Anastomosis System
Regulatory Class: Class II
Product Code: SAH
Dated: May 15, 2026
Received: May 18, 2026

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 device type. 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 as specified in special control (1). The special control requirements set forth in the classification 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 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 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
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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)*
K261630

Device Name
GI Windows Flexagon Plus OTOLoc System

Indications for Use *(Describe)*
The GI Windows Flexagon Plus OTOLoc System is intended for use in the creation of a side-to-side gastric-jejunum, gastric-ileum, jejunum-jejunum and ileum-ileum anastomoses in minimally invasive endoscopic 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 Plus OTOLoc 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.

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

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510(K) Summary
K261630

Contact Details:

Applicant Name: GI Windows, Inc.
Applicant Address: 480 Neponset St., Ste. 11-B1, Canton, MA 02021
Applicant Contact Telephone: 617 669 6181
Applicant Contact: Ms. Yverre Bobay
Applicant Contact Email: Yverre.bobay@giwindows.com

Device Name:

Trade Name: GI Windows Flexagon Plus OTOLoc System
Common Name: Self-Forming Magnet System
Submission Number: K261630
Classification Name: Magnetic Compression Anastomosis System
Regulation Number: 878.4816
Product Codes: SAH

Primary Predicate Device:

Device Trade Name: GI Windows' Flexagon Plus OTOLoc System
Common Name: Self-Forming Magnet System
Submission Numbers: K250541, K253550
Classification Name: Magnetic Compression Anastomosis System
Regulation Number: 878.4816
Product Codes: SAH

Limitations

The sale, distribution, and use of the Flexagon SFM Plus OTOLoc and Flexagon Systems are restricted to prescription use in accordance with 21 CFR 801.109.

Device Description Summary

The GI Windows Flexagon SFM Plus OTOLoc is magnetic compression anastomosis system, which is a surgical device used for the creation of anastomosis in minimally invasive surgery in the gastrointestinal tract. The system is comprised of self-forming magnets and includes the SNAP 2.0 endoscopic and FlexFire Universal laparoscopic delivery systems. The alternating dipoles of the Flexagon magnet drives magnetic self-alignment to prevent apposition. The anastomosis formation occurs over time once the remodeling of the targeted tissues is complete. The Flexagon magnets compress the opposing tissues which allows the body to dictate the time required for re-epithelialization. Compression and necrosis of tissue is achieved between magnet devices and is created by the 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 for most patients, but rarely magnets have taken up to 2 months to pass.

Intended Use/Indications for Use:

<u>Flexagon Plus OTOLoc</u>

The GI Windows Flexagon Plus OTOLoc System is intended for use in the creation of a side-to-side gastric-jejunum, gastric-ileum, jejunum-jejunum and ileum-ileum anastomoses in minimally invasive endoscopic 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 Plus OTOLoc System is intended for use in adult patients > 21 years.

Technological Comparison

The subject device, GI Windows Flexagon SFM Plus OTOLoc is not changing the fundamental magnetic compression anastomosis technology employed in the primary predicate device and has the same intended use and similar indications for use. The subject devices' Flexagon SFM is identical and delivery tools are the same as those previously cleared under K250541, K253550 and K243482. Only minor changes were made to the OTOLoc and the indications were expanded to include side-to-side gastric-jejunum & gastric-ileum anastomosis creation with Flexagon Plus OTOLoc.

Summary of Performance Data

The determination of substantial equivalence is based on an assessment of non-clinical performance data, the same tests as completed by the predicate device. Minor modifications were made only to the OTOLoc implant and all other system components remained the same as the predicate device. To verify that the OTOLoc design changes meet the functional and performance requirements, Flexagon SFM Plus OTOLoc and delivery tools underwent the following performance tests. The tests were performed on the subject devices using similar method and acceptance criteria as the predicate device (tests apply to all implants and delivery tools unless noted otherwise). Because no changes were introduced to the device beyond the otoloc component, data from the predicate device is used to support all remaining biocompatibility endpoints.

- Transportation Validation and Shipping test / ASTM D 4169: 2022
- Biocompatibility tests to address the OTOLoc design changes were completed. All patient-contacting components of Flexagon Plus OTOLoc 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)
    - SubChronic Toxicity (10993-11)
    - Corrosion Testing
- Compression force testing (Flexagon magnet)
- 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
- Packaging Validation
- Shelf-life testing

GLP Animal Studies

GLP animal studies were conducted to evaluate the Flexagon Plus OTOLoc and accessories for use in gastric, colorectal and small bowel anastomosis in a chronic porcine model. In all evaluations, the animals were survived to a minimum of 25 days and the magnets and OTOLocs were all expelled within 25 days.

In all evaluations, the Flexagon Plus OTOLoc device and the anastomoses created using the GI Windows suite of products performed as well as or better than the stapler control devices and anastomoses when evaluating tissue burst pressure and histological architecture of the healed tissue. The Flexagon Plus OTOLoc System met all the

usability, safety and effectiveness acceptance criteria predefined in the protocols. There were no device failures reported with the magnets. The usability of all devices during implant was reported as “Easy” or “Very Easy” by surgeons. Compared to common and accepted control anastomosis devices and procedures, the GI Windows device is safe, effective and capable of creating a durable gastrointestinal anastomosis in a chronic swine anastomosis model.

Clinical Testing

Clinical evaluation was conducted in patients using the Flexagon Plus OTOLoc System for creation of side-to-side gastric-jejunum and gastric-ileum anastomosis in a total of 85 patients and 84/85 patients completed the full 60-day follow up including studies conducted in Chile and India. The Magnets were delivered endoscopically and laparoscopically using the SFM Delivery Systems. The Magnets self-aligned due to their opposing polarity and were successfully placed with immediate fluidic flow through the OTOLoc and magnet in 100% of the cases. For 84/85 subjects, the magnets and OTOLoc mean expulsion time was 30.61 days. 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. No cases of internal hernias were reported during the study 60-day follow up. There were no cases of anastomotic leakage, infection and no deaths. There were no re-operations conducted within 30-days of implant achieving the Primary Endpoint of the clinical study. The device system performed safely and as intended to create patent anastomoses.

Postmarket Surveillance

The subject Flexagon Plus OTOLoc System will be subject to a postmarket surveillance study to address the generalizability of the device's safety and effectiveness for side-to-side gastric-jejunum and gastric-ileum anastomosis in U.S. patients, representative of the U.S. intended use population who are treated with the Flexagon Plus OTOLoc System.

Substantial Equivalence Conclusion

Based on the testing and evaluations completed, the GI Windows Flexagon SFM Plus OTOLoc System is as safe, as effective, and performs as well as the legally marketed predicate device, Flexagon SFM Plus OTOLoc (K253550, K250541). The subject device, GI Windows Flexagon SFM Plus OTOLoc System has demonstrated substantial equivalence to the predicate device based on the same intended use and similar Indications for Use, technological characteristics and performance testing.