August 01, 2025

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

Re: K250541
Trade/Device Name: Flexagon Plus OTOLoc System
Regulation Number: 21 CFR 878.4816
Regulation Name: Magnetic Compression Anastomosis System
Regulatory Class: Class II
Product Code: SAH
Dated: February 24, 2025
Received: February 24, 2025

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

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
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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)*
K250541

Device Name
Flexagon Plus OTOLoc System

Indications for Use *(Describe)*
Flexagon Plus OTOLoc System is intended for use in the creation of side to side jejunum-jejunum and ileum-ileum 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 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.

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510(K) Summary (K250541)

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:

Trade Name: Flexagon Plus OTOLoc System
Common Name: Self-Forming Magnet System
Submission Number: K250541
Classification Name: Magnetic Compression Anastomosis System
Regulation Number: 878.4816
Product Codes: SAH

Primary Predicate Device:

Device Trade Name: Self-Forming Magnet (FLEXAGON)
Common Name: Self-Forming Magnet System
Submission Number: K243482
Classification Name: Magnetic Compression Anastomosis System
Regulation Number: 878.4816
Product Codes: SAH

Secondary Predicate Device:

Device Trade Name: NiTi Medical Technologies, Ltd. Laparoscopic Compression Anastomosis Clip (CAC)
Submission Number: K043115
Classification Name: Clip, implantable
Regulation Number: 878.4300
Product Codes: FZP

Reference Device:

Device Trade Name: Davis and Geck, Inc. Valtrac Anastomosis Ring (BAR)
Submission Numbers: K913411, K931056
Classification Name: Staple, implantable
Regulation Number: 878.4750
Product Codes: GDW

Limitations

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

Device Description Summary

The Flexagon SFM Plus OTOLoc 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 self-forming magnets and includes the delivery system. The OTOLoc component provides

enterotomy preservation for immediate fluidic flow upon implant, while 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.

Intended Use/Indications for Use:

The GI Windows Flexagon Plus OTOLoc System is intended for use in the creation of side-to-side jejunum-jejunum and ileum-ileum 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 SFM Plus OTOLoc is intended for use in adult patients > 21 years.

Technological Comparison

The subject device, 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 device' magnetic strength is identical to that of the cleared Flexagon SFM (K243482) as the self-forming magnets are the same and within levels of other commercially cleared magnetic compression devices (GI Windows' FLEX SFM (K243213) and GT Metabolics' Mag DI (DEN240013)). Addition of the OTOLoc component to the Flexagon SFM + OTOLoc device to facilitate immediate flow in the intestinal lumen is the same technological feature as provided by other cleared devices: Valtrac (K913411) and NiTi Surgical Compression Anastomosis Clip (CAC) (K043115).

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. To verify that the device design meets the functional and performance requirements, Flexagon SFM Plus OTOLoc underwent the following performance testing. The tests were performed on the subject devices using similar method and acceptance criteria as the primary predicate device.

- Transportation Validation and Shipping test / ASTM D 4169: 2022
- Biocompatibility tests / ISO 10993 standards. 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 / Implantation (10993-11 and 10993-6)
    - Genotoxicity – Ames Assay / Mouse Lymphoma Assay (ISO 10993-3)
    - Chronic Toxicity (ISO 10993-11)
    - 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

- Chronic porcine survival testing was conducted over a 6-week period
- 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
- 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.

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 Plus OTOLoc System passed per ISO 10993-1.

Biocompatibility as performed on the magnet assembly (Tables 1-2) and delivery devices (Tables 3-4).

Table 1: Magnet & OTOLoc 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 • Silicone	**Contact Type** Surface Mucosal membrane **Contact Duration** Long Term (>30 days)

Table 2: Biocompatibility Testing Summary for Magnets & OTOLoc

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	Pass – non-pyrogenic

Test Performed	Test Method	Results
	evaluate device extracts for pyrogenicity risks.	
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	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 3: Delivery System Materials, Type and Duration of Contact

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

Table 4: 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

Magnetic Resonance (MR) Compatibility
The Flexagon System is MR unsafe.

GLP Animal Studies
GLP animal studies were conducted to evaluate the Flexagon Plus OTOLoc 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 Plus OTOLoc 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 Plus OTOLoc 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.

Clinical Testing

Clinical evaluation was conducted in 84 patients using the Flexagon Plus OTOLoc System for creation of side-to-side jejunum-jejunum and ileum-ileum anastomosis including studies conducted in the United States, Chile and India. The Magnets were sequentially delivered laparoscopically using the Delivery System. The Magnets self-aligned due to their opposing polarity and were successfully placed with immediate fluidic flow through the OTOLoc and magnet in all cases. For all subjects, the magnets and OTOLoc passed naturally with none requiring invasive re-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. 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 Flexagon SFM Plus OTOLoc System performed safely and as intended to create patent anastomoses with a profile as least as safe as commercially available and the primary predicate compression anastomosis device Flexagon SFM (K243482).

Postmarket Surveillance

The subject device will be subject to and incorporated into the same postmarket surveillance study as the predicate (K243482) 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 SFM Plus OTOLoc device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices, Flexagon SFM (K243482) and NiTi CAC (K043115). The subject device, GI Windows Flexagon SFM Plus OTOLoc System has demonstrated to be substantially equivalent to the predicate devices, Flexagon SFM based on the same intended use and similar Indications for Use, technological characteristics and performance testing.