January 09, 2026

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

Re: K253550
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: November 14, 2025
Received: November 14, 2025

Dear Westwood 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. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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).

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253550

Device Name
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 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 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
(K253550)

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: TBD
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 Number: K250541
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 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 a 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 Plus OTOLoc System 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 indications for use. The subject device' Flexagon and OTOLoc implant components are identical to those of the cleared predicate device (K250541). Only the delivery tools were modified to consolidate two tools into one to deliver both the Flexagon and OTOLoc implants sequentially and to support ease of use.

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 delivery tool 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)
- Usability testing using a bench-top laparoscopic model
- Human clinical usability feedback and testing
- Packaging Validation
- Simulated use testing

Substantial Equivalence Conclusion

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