



June 21, 2024

G-Surg GmbH
% Anna Pocsai
Consultant
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Friedrich-Miescher-StraBe 9
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Germany

Re: K233240
Trade/Device Name: GERDX-System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODE
Dated: May 24, 2024
Received: May 24, 2024

Dear Anna Pocsai:

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.

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.

Assistant Director

DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices

OHT3: Office of GastroRenal, ObGyn,

General Hospital and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K233240

Device Name

GERDX-System

Indications for Use (Describe)

Indications for Use (Describe)

The GERDX®-System is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

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.

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Table of Content of Volume 5: Premarket Notification 510(k) Summary

TABLE OF CONTENT OF VOLUME 5: PREMARKET NOTIFICATION 510(K) SUMMARY	5-1
5. PREMARKET NOTIFICATION 510(K) SUMMARY	5-1
1. CONTACT DETAILS	5-1
2. DEVICE NAME	5-1
3. LEGALLY MARKETED PREDICATE DEVICES	5-1
4. DEVICE DESCRIPTION SUMMARY	5-1
5. INTENDED USE / INDICATIONS FOR USE:.....	5-2
6. COMPARISON OF CHARACTERISTICS	5-2
6.1 INDICATIONS FOR USE COMPARISON	5-2
6.2 TECHNOLOGICAL COMPARISON.....	5-2
7. NON-CLINICAL AND CLINICAL TESTS SUMMARY & CONCLUSION	5-3

5. Premarket Notification 510(k) Summary

1. CONTACT DETAILS

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Date prepared: June 17, 2024

2. DEVICE NAME

Trade Name: GERDX-System
Common Name: Endoscope accessory
Classification Name: Endoscopic Suture/Plication System, Gastroesophageal Reflux Disease (Gerd), Class: II
Regulation Number: 876.1500
Product Code: ODE

3. LEGALLY MARKETED PREDICATE DEVICES

Endoscopic Plication System; Plicator™ (K071553); **Product Code: ODE**

4. DEVICE DESCRIPTION SUMMARY

The GERDX-System is a sterile application and suture system indicated for the treatment of symptomatic chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

The GERDX-System consist of following procedural components: GERDX-Applicator, GERDX-Tissue Retractor, GERDX-Suture System and the GERDX-Guide Wire.

The Suture System and the Tissue Retractor are loaded onto the Applicator. The Guide Wire is placed within the antrum of the stomach by standard procedure. By use of the Guide Wire, the Applicator is introduced orally and advanced through the esophagus into the stomach. After removing the Guide Wire a thin profile gastroscope is inserted into a channel within the Applicator and the Applicator is positioned under direct endoscopic visualization at the target location within the gastrointestinal (GI) tract. The Tissue Retractor is advanced out of the distal tip of the Applicator. Gastric tissue is engaged by the Tissue Retractor and withdrawn into the Applicator, thereby pulling the tissue into the open arms of the Applicator. The arms of the Applicator are then closed to grasp and approximate the target tissue. The Suture System is then deployed to transmurally affix the GI tissue. The procedure is repeated to deploy additional Suture Systems if necessary. The number of Suture Systems that are placed will vary based on patient anatomy and physician's judgement. Parts of the Suture System remain within the patient.

5. INTENDED USE / INDICATIONS FOR USE:

The GERDX®-System is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

6. COMPARISON OF CHARACTERISTICS

6.1 INDICATIONS FOR USE COMPARISON

With the exception of the device name, the indications for use statements are identical.

6.2 TECHNOLOGICAL COMPARISON

The proposed GERDX-System is clinically, biologically, and technologically identical of the proposed predicate device (K071553). The devices differ only in some technological details.

Summary of differences:

- GERDX-Applicator: By the predicate device force is transmitted manually via cables and pulls, whereas for the GERDX-System force is transmitted via a manually operated hydraulic system. However, this modification shows several improvements in safety-relevant aspects.
- GERDX-System: All components of GERDX-System are sterile, while some components of predicate device are non-sterile and reusable. Therefore, there are no labelling regarding of cleaning and disinfection is present on the label of the GERDX-System
- GERDX-System contains an additional component, a Guide Wire, which had to be purchased separately by the predicate device. The component Guide Wire is identical for the two devices.
- GERDX-Suture: same design, except of the material of the surgical suture used. However, the suture for the GERDX-System is cleared by FDA and its biocompatibility has been confirmed.

7. NON-CLINICAL AND CLINICAL TESTS SUMMARY & CONCLUSION

Bench tests:

Procedure-related bench tests were provided to assess the forces associated with a full thickness plication. Side by side tests were performed with GERDX-System and with the proposed predicate. The results of these tests confirm that the GERDX-System and Plicator EPS have equivalent technological characteristics, designs, and operational properties and support the performance and safety of the GERDX-System.

Biocompatibility of GERDX-System met the acceptance criteria according to ISO 10993-1:2018.

Clinical testing

Two peer-reviewed articles have been published whereas GERDX-System was proved as an effective minimally invasive endoscopic intervention to control GERD.

Animal testing

Animal studies performed on a porcine model in a GLP-conform laboratory demonstrated the safety and feasibility of GERDX-System.

Based on indications for use, clinical evaluation, performance- and biocompatibility tests presented in this premarket notification, the GERDX-System is substantially equivalent to the Plicator and do not raise new issues of safety and effectiveness.