April 26, 2024

EndoGastric Solutions, Inc.
% John J. Smith
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
Columbia Square
Washington, District of Columbia 20004

Re: K240879
Trade/Device Name: EsophyX Z+ Device with SerosaFuse Fasteners and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODE
Dated: March 29, 2024
Received: March 29, 2024

Dear John J. Smith:

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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240879

Device Name

EsophyX Z+ Device with SerosaFuse Fasteners and Accessories

Indications for Use *(Describe)*

The EndoGastric Solutions EsophyX Z+ Device with SerosaFuse Fasteners and Accessories is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the junction and reduce hiatal hernia ≤ 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease. Patients with hiatal hernias larger than 2cm may be included, when a laparoscopic hiatal hernia repair reduces the hernia to 2cm or less.

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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510(K) SUMMARY

EndoGastric Solutions, Inc. EsophyX Z+ Device with SerosaFuse Fasteners and Accessories

Submitter

EndoGastric Solutions, Inc.
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Date Prepared: March 29, 2024

Name of Device: EsophyX Z+ Device with SerosaFuse Fasteners and Accessories

Classification Name: 21 CFR 876.1500, Endoscope and accessories – Endoscopic Suture/Plication System, Gastroesophageal Reflux Disease (Gerd)

Regulatory Class: II

Product Code: ODE

Predicate Device: EndoGastric Solutions, Inc., EsophyX Z Device with SerosaFuse Fasteners and Accessories (K172811)

Device Description

The EsophyX Z+ Device with SerosaFuse Fasteners and Accessories is a prescription use only, disposable, single-use, sterile system consisting of an all-mechanical, flexible fastener delivery device with user controls outside the patient's body. The transoral device and tissue fasteners are provided sterile by ethylene oxide (EO). The delivery device is limited contact and materials include acrylic/polycarbonate plastics, machined aluminum, stainless steel, nitinol wire, UV cured adhesives, pellethane and nylon.

The permanent contact, implantable SerosaFuse tissue fasteners are constructed of injection molded polypropylene and are of a strength equivalent to 3-0 suture. The SerosaFuse Implantable Fastener Cartridge is dual-lever containing 20 fasteners, with 10 fasteners in each lever, and is designed to be removable. Each fastener consists of a leading leg, interconnecting web and trailing leg. The fastener's unique design allows it to be loaded onto a stylet, passed into and down a small delivery lumen of the device and subsequently delivered through apposed tissue surfaces in the GI tract. When deployed in tissue, the fastener serves as a suture-like implantable.

The system is used in an operating room environment, using the Transoral Incisionless Fundoplication (TIF) procedure. The EsophyX Z+ device deploys the SerosaFuse fastener during an endoscopic procedure. A separate commercial endoscope operating independently

down the center of the device's flexible shaft lumen provides visualization of the procedure from device insertion through extraction. The EsophyX Z+ device is capable of transoral tissue approximation, ligation, and full thickness plication in the GI tract. The process essentially mimics the standard surgical technique of grasping tissue and apposing/approximating the tissue, piercing, and suturing the tissue fold. Each of these steps is controlled at the device proximal end, though plication, ligation and gastroesophageal valve formation is accomplished at the distal end of the device.

Intended Use / Indications for Use

The subject and predicate EsophyX devices are both intended for transoral tissue approximation, plication and fastening of tissue in the GI tract, for the endoluminal treatment of gastroesophageal reflux disease. The subject device's indications for use are as follows:

The EndoGastric Solutions EsophyX Z+ Device with SerosaFuse Fasteners and Accessories is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the junction and reduce hiatal hernia ≤ 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease. Patients with hiatal hernias larger than 2cm may be included, when a laparoscopic hiatal hernia repair reduces the hernia to 2cm or less.

Summary of Technological Characteristics

The technological characteristics of the EsophyX Z+ device are largely unchanged from the EsophyX Z predicate device, which was cleared in K172811. This 510(k) submission primarily proposes changes to the instructions for use and other device labeling. A table comparing the key features of the subject and predicate devices is provided below.

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

	EsophyX Z+ (Subject Device)	**EsophyX Z (Predicate Device, K172811)**
Classification	21 CFR 876.1500, Endoscope and accessories (Class II)	21 CFR 876.1500, Endoscope and accessories (Class II)
Product Code	ODE (Endoscopic Suture/Plication System, Gastroesophageal Reflux Disease (Gerd))	ODE (Endoscopic Suture/Plication System, Gastroesophageal Reflux Disease (Gerd))
Intended Use	The EsophyX Z+ device is intended for transoral tissue approximation, plication and fastening of tissue in the GI tract, for the endoluminal treatment of gastroesophageal reflux disease.	The EsophyX Z device is intended for transoral tissue approximation, plication and fastening of tissue in the GI tract, for the endoluminal treatment of gastroesophageal reflux disease.

	EsophyX Z+ (Subject Device)	EsophyX Z (Predicate Device, K172811)
Indications for Use	The EndoGastric Solutions EsophyX Z+ Device with SerosaFuse Fasteners and Accessories is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the junction and reduce hiatal hernia ≤ 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease. Patients with hiatal hernias larger than 2cm may be included, when a laparoscopic hiatal hernia repair reduces the hernia to 2cm or less.	The EndoGastric Solutions EsophyX Z+ Device with SerosaFuse Fasteners and Accessories is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the junction and reduce hiatal hernia ≤ 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease. Patients with hiatal hernias larger than 2cm may be included, when a laparoscopic hiatal hernia repair reduces the hernia to 2cm or less.
User Population	Interventional Gastroenterologists and Surgeons	Interventional Gastroenterologists and Surgeons
Technological Characteristics	The system is a prescription use only, disposable, single-use, sterile system consisting of an all mechanical, flexible fastener delivery device with user controls outside the patient's body. The transoral device and tissue fasteners are provided sterile (EO). The tissue fasteners are equivalent to 3.0 suture and are permanent implants.	The system is a prescription use only, disposable, single-use, sterile system consisting of an all mechanical, flexible fastener delivery device with user controls outside the patient's body. The transoral device and tissue fasteners are provided sterile (EO). The tissue fasteners are equivalent to 3.0 suture and are permanent implants.
Major Components	EsophyX Z+ Fastener Delivery Device SerosaFuse Fastener Cartridge and Fasteners	EsophyX Z Fastener Delivery Device SerosaFuse Fastener Cartridge and Fasteners
Accessories	Endoscope Compatibility Tool	Endoscope Compatibility Tool
Safety Features	Safety features include safe sharps storage, fastener delivery lockout, and prevention of tissue over-plication	Safety features include safe sharps storage, fastener delivery lockout, and prevention of tissue over-plication
Biocompatibility	Meets the requirements of ISO 10993-1	Meets the requirements of ISO 10993-1
Sterilization	Ethylene Oxide; meets requirements of ISO 10993-7	Ethylene Oxide; meets requirements of ISO 10993-7

	EsophyX Z+ (Subject Device)	**EsophyX Z (Predicate Device, K172811)**
Standards with which the Device Complies	ISO 11135 ISO 11607-1 ISO 11737-1	ISO 11135 ISO 11607-1 ISO 11737-1

Performance Data

Non-clinical testing was conducted to demonstrate that the EsophyX Z+ device is as safe and effective as the predicate device:

- Labeling verification
- Benchtop performance testing, including evaluation of device forces, fastener loading and deployment, and dimensional verification

In all instances, the EsophyX Z+ device functioned as intended and demonstrated passing results.

Conclusions

The EsophyX Z+ device is as safe and effective as the predicate EsophyX Z device (K172811). The EsophyX Z+ device has the same intended uses and indications, and similar technological characteristics and principles of operation as its predicate device. In addition, the minor differences between the EsophyX Z+ device and its predicate devices raise no new issues of safety or effectiveness. Thus, the EsophyX Z+ Device with SerosaFuse Fasteners and Accessories is substantially equivalent.