



Food and Drug Administration
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Silver Spring, MD 20993-0002

June 22, 2017

EndoGastric Solutions, Inc.
Steve J. Hoffman
Corporate Compliance Officer
18109 NE 76th Street, Suite 100
Redmond, WA 98052

Re: K171307
Trade/Device Name: EsophyX2 HD Device with SerosaFuse Fasteners and Accessories,
EsophyX Z Device with SerosaFuse Fasteners and Accessories
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODE
Dated: April 24, 2017
Received: May 3, 2017

Dear Steve J. Hoffman:

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 (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. 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](#).

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,


Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K171307

Device Name

EsophyX2 HD Device with SerosaFuse Fasteners and Accessories,
EsophyX Z Device with SerosaFuse Fasteners and Accessories

Indications for Use (Describe)

EsophyX2 HD Device with SerosaFuse Fasteners and Accessories: The EndoGastric Solutions EsophyX2 HD 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 gastroesophageal junction and reduce hiatal hernia ≤ 2 cm 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.

EsophyX Z Device with SerosaFuse Fasteners and Accessories: 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 gastroesophageal junction and reduce hiatal hernia ≤ 2 cm 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

EsophyX[®]₂ HD and EsophyX Z Fastener Delivery Devices with SerosaFuse Fasteners and Accessories

Submitter

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Date Prepared: April 24, 2017

Device(s) Trade Names: EsophyX₂ HD Device with SerosaFuse Fasteners and Accessories
EsophyX Z Device with SerosaFuse Fasteners and Accessories

Common Name: Endoscopic Clip Applier, Implantable Fastener and Accessories
Classification Name(s): Endoscope and Accessories
Product Code/ Regulation: ODE / 21 CFR 876.1500
Classification: Class II

Predicate Devices: EndoGastric Solutions, EsophyX₂ HD, K142113
EndoGastric Solutions, EsophyX Z, K160960

Reference Devices: N/A

Device Description:

The subject EsophyX devices are unchanged from the currently cleared devices. The principles of operation for the devices are the same and also remain unchanged from the prior clearances. The indications for use for both models are identical.

The EndoGastric Solutions EsophyX Device models (EsophyX₂ HD and EsophyX Z, K142113 and K160960, respectively) with SerosaFuse Fasteners and Accessories are a prescription use only, disposable, single use system consisting of an all mechanical, flexible fastener delivery device with user controls outside the patient's body. The devices are used in an operating room environment, using the Transoral Incisionless Fundoplication (TIF) procedure.

The device is classified as a surface device, mucosal membrane contacting with limited duration. The fastener classification is an implant, with permanent tissue/bone contact. Materials include acrylic/polycarbonate plastics, machined aluminum, stainless steel, nitinol wire, UV cured adhesives, pellethane and nylon.

The implantable tissue fasteners are constructed of injection molded polypropylene.

These transoral devices and tissue fasteners are provided sterile (EO). A separate, commercial endoscope operating independently down the center of the devices' flexible shaft lumen provides visualization of the procedure at all times, from device insertion through extraction. Two fasteners are loaded from a replaceable fastener cartridge containing ten fasteners for each channel. The loaded fasteners are pushed from the proximal device end, to the distal end down two separate channels via lumens in a flexible shaft where they are then in position ready for deployment into tissue. The operator, controlling the distal end of the devices through the mechanical controls at the proximal end of the devices, captures and positions a fold of tissue at the gastroesophageal junction. The fastener controls deploy both fasteners simultaneously in the EsophyX Z model, or individually in the EsophyX₂ HD model, at the captured tissue position. This creates a permanent surgical partial fundoplication. Additional fasteners are used as needed to complete the valve restoration.

Intended Use / Indications for Use

Both EsophyX₂ HD and Z Fastener Delivery Devices with SerosaFuse Fasteners and accessories are intended for transoral tissue approximation, plication and fastening of tissue in the GI tract, for the endoluminal treatment of gastroesophageal reflux disease.

The Indications for Use is as follows:

The EndoGastric Solutions EsophyX Device models (EsophyX₂ HD and EsophyX Z) with SerosaFuse Fasteners and Accessories are indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and are 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 gastroesophageal junction and reduce hiatal hernia ≤ 2 cm 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.

Indications for Use expansion rationale

The Indications for Use statement differs from the predicates only in the last sentence which includes the population of patients with hiatal hernias larger than 2cms, if the hiatal hernia is first repaired in a separate operation bringing the dimension of the hernia below the devices' limit of 2cm or less. The added sentence does not change the originally established devices' Indications for Use and does not affect the technological characteristics, design or manufacturing of the devices. The Indications for Use expansion, does not change the intended therapeutic, or surgical use of the device and does not affect the safety and effectiveness of the device when used as labeled.

Summary of Technological Characteristics

Both EsophyX models are cleared for the same indications for use with the subject devices unchanged from the corresponding predicates (please reference K142113 and K160960). Both devices use the same method of loading fasteners at the proximal end of the device and moving them down to the distal end in preparation of deployment. Tissue is retracted, secured in position, plicated and fastened in the same manner. Both use the TIF procedure.

As with the identical predicate device, the EsophyX Z differs in design in the operator controls on the proximal end when compared to the EsophyX₂ HD. In the EsophyX₂ HD, posterior and anterior fasteners can be deployed using individual controls. In the EsophyX Z device, these controls have been automated with a mechanical trigger, which deploys both fasteners at the same time.

Furthermore, for the original EsophyX Z device (K143645), the EsophyX₂ HD device (K142113) was used as the predicate without additional in vivo data needed for substantial equivalence. Thus, the Agency previously viewed the clinical data submitted with the original EsophyX₂ HD device applicable to the EsophyX Z device. Therefore, because the devices have the same indications for use and are highly similar technologically, the company will be relying on the same clinical data as presented below in this submission for both devices.

No technological differences exist between the subject and predicate devices.

Performance Data

As both submission devices are identical to the predicates devices, the performance characteristics remain the same as those cleared previously in submissions K142113 and K160960.

As previously cleared in the referenced submissions, both products are purely mechanical, have no device specific guidance documents, consensus standards are referenced, verification and validation testing was completed successfully and biocompatibility testing passed. In all instances, both devices function as intended and operation observed continues as designed.

Because there are no device changes, the safety and effectiveness profiles for both devices remain identical to the predicate devices.

The expanded indications for use for the EsophyX devices is supported using clinical data from literature. Labeling to include patients with hiatal hernias greater than two centimeters when a laparoscopic hiatal hernia repair reduces the hernia to 2cm or less does not affect either device's previous 510(k) clearances.

The indications are supported by clinical outcomes in the literature on 163 patients who have undergone the procedure of hiatal hernia repair before TIF with favorable results. This literature is summarized briefly below.

1. *Ihde, G et al. Short-term safety and symptomatic outcomes of transoral incisionless fundoplication with or without hiatal hernia repair in patients with chronic*

gastroesophageal reflux disease. The American Journal of Surgery, 2011 Dec; 202 (6):740-6.

Forty-eight (48) patients underwent TIF using the EsophyX device. Patients who presented with a hiatal hernia 3 cm or more in the greatest transverse diameter underwent laparoscopic HHR before TIF (n=18). There were no long-term postoperative complications. At the median follow-up of 6 months, 73% of patients normalized the GERD-HRQL score ($p < .001$), 73% of patients eliminated the heartburn, 76% of patients eliminated the regurgitation, 67% of patients reported elimination of atypical symptoms, 76% of patients were off daily proton pump inhibitors (PPIs) and 88% of patients were satisfied with their current health condition.

2. *Chang, C et al. Laparoscopic Hiatal Hernia Repair in 221 Patients: Outcomes and Experience. Journal of the Society of Laparoendoscopic Surgeons, January-March 2016 Volume 20 Issue 1 e2015.00104.*

This analysis included patients who underwent HHR with a simultaneous bariatric procedure (n=122), TIF (n=46), Nissen fundoplication (n=10) or HHR alone (n=33). The greatest GERD-HRQL score improvement (average 20.5 points) was observed in patients who underwent HHR with a fundoplication procedure (Nissen/TIF), and was statistically significant. Most complications were minor (dysphagia, nausea and vomiting).

3. *Janu, P et al. Transoral incisionless fundoplication (TIF) procedure with EsophyX device following laparoscopic hiatal hernia repair: a two-center community hospital experience of 99 patients.*

Approximately 99 patients underwent the TIF procedure with the EsophyX device following HHR and were given GERD-HRQL, RSI, and GSRS questionnaires at screening, 6 months and 12 months post-procedure. HRQL scores were improved 85% for all six heartburn questions and 7 regurgitation questions, while 50% improvement was noted for bloating, dysphagia and odynophagia. The RSI scores for hoarseness, throat clearing, excess mucus, coughing and chest pain also improved as well, from 50% to 80%. The GSRS questions on heartburn and regurgitation showed 80% improvement while bloating and dysphagia improved by more than 50%. All these results were durable at 6 and 12 months follow up. There were no adverse effects reported.

Conclusions

The only change compared to the predicate EsophyX devices clearance is the inclusion of hiatal hernia repair followed by the TIF procedure, expanding the Indications for Use. Per the clinical literature, Physicians are using the device in patients with hiatal hernias >2cm in whom the hiatal hernia repair is performed, reducing it below 2cm, under the practice of medicine, with positive results. Therefore, the expansion of the indications for use, based on the literature search are substantiated.

As the subject devices and the predicate devices are the same, the EsophyX₂ HD and EsophyX Z are as safe and effective as the predicate EsophyX₂ HD and EsophyX Z devices. Both devices have the same intended uses and indications, technological characteristics,

and principles of operation as their predicate devices. The expanded Indications for Use do not alter the intended therapeutic use of the device and do not affect its safety and effectiveness when used as labeled. Device performance data remains the same and is therefore as safe and effective as the predicate devices. Thus, the EsophyX₂ HD and EsophyX Z are substantially equivalent to their predicates.