



Food and Drug Administration
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May 1, 2016

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

Re: K160960
Trade/Device Name: 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 1, 2016
Received: April 5, 2016

Dear Steven 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 yours,


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)

K160960

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 gastroesophageal junction and reduce hiatal hernia ≤ 2 cm in size in patients with symptomatic chronic gastroesophageal reflux disease.

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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Section 1. Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K160960

Applicant Information [807.92(a)(1)]:

Date Prepared: April 27, 2016
Name: EndoGastric Solutions, Inc.
Address: 18109 NE 76th St. Suite 100
Redmond, WA 98052
Phone: 425-307-9200
Fax: 425-307-9201

Contact Person: Steven J Hoffman
Phone Number: 425.307.9226
Office: 425.307.9226
Facsimile Number: 425.307.9201

Device Information [807.92(a)(2)]:

Device Trade Name: 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 Device(s) [807.92(a)(3)]:

The predicate device is the EndoGastric Solutions EsophyX Z System cleared via 510(k) # K143645.

Device Description: [807.92(a)(4)]:

The EndoGastric Solutions EsophyX Z Device with SerosaFuse Fasteners and Accessories is 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 transoral device and tissue fasteners are provided sterile (EO). 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. Two polypropylene fasteners are loaded from a replaceable fastener cartridge containing ten fasteners for each channel. The loaded fasteners are pushed simultaneously 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 for deployment into the tissue. The operator, controlling the distal end of the device through the mechanical controls captures and positions a fold of tissue at the gastroesophageal junction. The delivery trigger mechanism deploys both fasteners simultaneously at the captured tissue

510(k) Summary (Continued):

position, creating a permanent surgical fundoplication. Additional fasteners are used as needed to complete the valve restoration.

Intended Use / Indications for Use [807.92(a)(5)]:

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.

Summary of the Technological Characteristics compared to the Predicate Device [807.92(a)(6)]:

Transoral incisionless fundoplication is the technological principle for both the subject and predicate devices and is based on transoral instrumentation for approximating, ligating and permanently joining esophageal/gastric tissue, restoring the valvular functionality at the gastroesophageal junction and reducing gastroesophageal reflux.

Both subject and predicate devices are based on the following technological elements:

- A flexible shaft, fastener delivery device inserted transorally using a separate, appropriately sized endoscope to provide visualization of the entire procedure
- Polypropylene, H-shaped fasteners acting as permanent implants to secure tissue
- Use of tissue invagination to correct hiatal hernias up to 2cm
- Mechanical user interface controls on the delivery device which control fastener loading, tissue capture, fastener positioning at the distal device end and fastener deployment through the captured tissue

The differences between the modified and predicate device include minor control changes:

- A minor housing change adds more positive helical retractor lock stops
- A retractor lock mechanism modification allows the retractor to be pulled back while the lock is engaged.
- An open-side tissue mold control mechanism modification to automatically open the mold when tension is removed on the closed-side.

Several non-operator control changes were made: to reduce device part count, reduce cost, increase manufacturability, or as an iterative design refinement.

Two patient contacting material changes were made by adding colorant to the same material cleared in the predicate device. Three other non-patient contacting materials were also changed. All were included in system biocompatibility testing.

510(k) Summary Continued:

Performance Data on which Substantial Equivalence is Based [807.92(b)(1) and (2)]:

Verification and validation testing results provided evidence the device modifications met the design specifications and user needs. Testing included dimensional, mechanical and performance specifications. As part of design validation, cadaver and animal labs were performed verifying fastener deployment in various tissue types. Clinical evaluation as part of design validation was not required for the modifications made to the EsophyX Z to establish safety and effectiveness equivalence.

As a result of two different patient contacting materials being incorporated at the distal end of the modified EsophyX Z device, a biocompatibility evaluation was performed. Indicated testing included cytotoxicity, sensitization, and irritation or intracutaneous reactivity testing. Test results demonstrated the modified EsophyX Z meets all relevant biocompatibility testing requirements.

Conclusions Drawn from Performance Data [807.92(b)(3)]

The verification, validation and biocompatibility testing demonstrate the modified EsophyX Z is as safe and effective and performs as well as the predicate device referenced in this submission. The device meets product specifications and user requirements.

Additional Information [807.92(d)]

None.

Summary:

Based upon the intended use, indications for use, product technical information, performance testing and biocompatibility information provided in this premarket notification, the modified EsophyX Z device has been shown to be substantially equivalent to the predicate EsophyX Z device, when used as intended.