October 19, 2017

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

Re: K172811
Trade/Device Name: EsophyX Z Device with SerosaFuse Fasteners and Accessories
EsophyX$_2$ HD Device with SerosaFuse Fasteners and Accessories
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODE
Dated: September 26, 2017
Received: October 4, 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 (DICE) 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 (DICE) 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,

Joyce M. Whang -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K172811

Device Name

EsophyX Z Device with SerosaFuse Fasteners and Accessories

EsophyX$_2$ HD Device with SerosaFuse Fasteners and Accessories

Indications for Use *(Describe)*

EsophyX$_2$ HD Device with SerosaFuse Fasteners and Accessories: The EndoGastric Solutions EsophyX$_2$ 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 ≤ 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.

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 ≤ 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.

510(k) Summary

EsophyX®$_2$ HD and EsophyX Z Fastener Delivery Devices

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: _____

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

Date Prepared:	August 26, 2017
Name:	EndoGastric Solutions, Inc.
Address:	18109 NE 76th St. Suite 100 Redmond, WA 98052
Phone:	425-307-9200
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Contact Person:	Steven J Hoffman
Phone Number:	425.307.9226
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Device Information [807.92(a)(2)]:

Device Trade Name:	EsophyX® Z Device with SerosaFuse Fasteners and Accessories EsophyX$_2$ HD 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)]:

EndoGastric Solutions, EsophyX$_2$ HD, EndoGastric Solutions, EsophyX Z, K171307

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

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 clearance. The indications for use for both models are identical.

The EndoGastric Solutions EsophyX Device models (EsophyX$_2$ HD and EsophyX Z, K171307) with SerosaFuse Fasteners and Accessories are a prescription use only, disposable, single use systems 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 limited contact and materials include acrylic/polycarbonate plastics, machined

510(k) Summary (Continued):

aluminum, stainless steel, nitinol wire, UV cured adhesives, pellethane and nylon.

The permanent contact, 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 EsophyX$_2$ 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 [807.92(a)(5)]:

Both EsophyX$_2$ 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 for both products 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 ≤ 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 the Technological Characteristics compared to the Predicate Device [807.92(a)(6)]:

Both EsophyX models are cleared for the same indications for use with the subject devices unchanged from the corresponding predicates (please reference K171307). 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 EsophyX$_2$ HD. In the EsophyX$_2$ 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.

510(k) Summary (Continued):

Further, the EsophyX Z device/EsophyX$_2$ HD devices (K171307) were used as the predicate without additional in vivo data needed for substantial equivalence as there are no changes made to the devices for this specification change proposal. Therefore, the devices have the same indications for use and are identical technologically.
No technological differences exist between the subject and predicate devices.

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

As both submission devices are identical to the predicates devices, the performance characteristics remain the same as those cleared previously in submission K171307.

As previously cleared in the referenced submission, both products are purely mechanical, have no device specific guidance documents, consensus standards are referenced, verification and validation testing remains unchanged as well as biocompatibility testing. 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 engineering specification change to increase the upper, design specification limit for the clamping pressure of the current devices' operational feature which temporarily clamps apposed tissue until a fastener is deployed to hold tissue together is proposed to provide a moderate increase in margin due to variations in the manufacturing process. This could cause the clamping pressure to exceed the currently cleared specification due to minor variations in the control system drag within each device. This specification change is supported by literature.

Based on the data presented in the literature, we attest the product specification change for the EsophyX$_2$ HD and EsophyX Z devices does not change either device's operation, safety or effectiveness.

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

With the only change compared to the predicate EsophyX devices' clearance is a change to the product specification allowing a moderate increase in the upper limit of the temporary Tissue Mold clamping pressure occurring during each fastener deployment, no change is seen in the performance of either subject device.

As the subject devices and the predicate devices are the same, the EsophyX$_2$ HD and EsophyX Z are as safe and effective as the predicate EsophyX$_2$ 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 specification change does not alter the intended therapeutic use of the devices and does not affect 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 EsophyX$_2$ HD and EsophyX Z are substantially equivalent to their predicates.

Additional Information [807.92(d)]:

None.

Concluding Statements:

As the proposed and predicate devices remain the same in design and use, the proposed EsophyX$_2$ HD and EsophyX Z are as safe and effective as the predicate devices. All devices have the same intended use and indications, technological characteristics, and principles of operation.

The specification change to increase the margin for the upper clamping pressure limit does not alter the intended therapeutic use of the device and does not affect its safety and effectiveness when used as labeled. Device performance data, i.e., tissue clamping performance, remains the same and is therefore as safe and effective as the predicate devices. Thus, the proposed devices are substantially equivalent to the predicates.