DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 30, 2014

EndoGastric Solutions, Inc.
% Michael A Daniel
Consultant
Daniel & Daniel Consulting, LLC
Contact Address

Re: K142113
Trade/Device Name: EsophyX®2 HD 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: September 12, 2014
Received: September 15, 2014

Dear Michael A Daniel ,

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 Fisher
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 below.

510(k) Number *(if known)*
K142113

Device Name
EndoGastric Solutions EsophyX® 2 HD Device with SerosaFuse Fasteners and Accessories

Indications for Use *(Describe)*
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.

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.

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Section 7. 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: _____

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

Date Prepared: August 2, 2014

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

Contact Person: Michael A Daniel, Consultant
Phone Number: (415) 407-0223
Office: (775) 392-2970
Facsimile Number: (775) 392-2972

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

Device Trade Name: 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)]:

The predicate device is the EndoGastric Solutions EsophyX2 System cleared via 510(k) # K092400.

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

The EndoGastric Solutions EsophyX®2 HD Device with SerosaFuse Fasteners and Accessories consists of an all mechanical, flexible fastener delivery device with user controls outside the patient's body and sterile polypropylene fasteners delivered transorally through a flexible shaft into the GI tract via a common delivery mechanism comprised of three elements: a stylet, a pusher rod, and a delivery tube. All three fastener delivery elements run the length of the delivery device. The stylet runs down the inside of the lumen of the delivery tube and the pusher rod rides over the length of the stylet. The stylet is designed to pierce and hold the desired tissue plication in place and guide the fastener into position.

510(k) Summary Continued:

There are two separate tubes or channels in the device, referred to as the posterior and anterior channels. A fastener is loaded mechanically onto the stylet via a replaceable fastener cartridge containing ten fasteners for each channel. To load, the fastener cartridge lever is depressed, which snaps a fastener onto the stylet. The fastener is then pushed down the stylet from the proximal handle assembly to the distal tissue port via the pusher rod where it is then ready to be deployed into the tissue. When the desired tissue approximation/ plication is achieved, the pusher rod is used to push the fastener into the tissue, guided by the stylet which precedes it into the tissue. The leading leg of the fastener slides along the stylet into the tissue. Slight additional pressure advances the pusher causing the leading leg of the fastener to disengage from the stylet and the fastener then seats across the desired tissue plication. A new fastener is loaded proximally in the device at the loading port, after retracting the pusher rod. The loading and fastening procedure can be repeated.

The device is provided sterile and is a single use device.

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

The EndoGastric Solutions EsophyX®$_2$ HD Device with SerosaFuse Fasteners and Accesories 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 $\leq$ 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease.

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

No change is being made to the fundamental technology and operating principle of the previously cleared EsophyX2 System used in this submission as a predicate device (K092400). The EsophyX®$_2$ HD device is identical to this predicate device, only differing by the overall shaft diameter of the device, which has been increased to accommodate high definition (HD) endoscopes. The indications for use is unchanged. In summary:

- same indications for use;
- same operating principle;
- incorporates the same basic design with a larger shaft diameter (60Fr versus 54Fr);

510(k) Summary Continued:

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

Verification and validation testing provides proof that the modifications meet the design specifications and user needs, and biocompatibility testing provides evidence that the EsophyX®$_2$ HD device meets the biocompatibility requirements. Testing included dimensional, mechanical, and performance testing.

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

The verification and validation testing demonstrate that the EsophyX®$_2$ HD 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 EsophyX®$_2$ HD device has been shown to be substantially equivalent to the EsophyX®2 System, when used as intended. The EsophyX®$_2$ HD device has been verified and validated to be compatible with high definition endoscopes that are used in these applications.