SECTION 12. 510(K) SUMMARY

NOV - 6 2009

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: TBD

Applicant Information:

Date Prepared:	July 24, 2009
Name:	EndoGastric Solutions, Inc.
Address:	8210 154th Avenue N.E. Redmond, WA 98052 Phone: 425 307 9200 Fax: 425 307 9201
Contact Person:	Steve Hoffman
Phone Number:	Office: 425-307-9226
Facsimile Number:	(425) 307-9201

Device Information:

Classification:	Class II
Trade Name:	EndoGastric Solutions EsophyX2 System
Common Name:	Endoscopic Clip Applier, Implantable Fastener and Accessories
Classification Name:	Endoscope and Accessories (21 CFR 876.1500, Product Code ODE)

Predicate Device:

The EndoGastric Solutions EsophyX Device with SerosaFuse Fastener is substantially equivalent in intended use and method of operation to a combination of the following predicate device:

K071651 - EndoGastric Solutions EsophyX System with SerosaFuse Fastener and accessories

Device Description:

The EndoGastric Solutions, EsophyX2 device with SerosaFuse Fasteners consist 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.

There are two separate tubes or channels in the device, referred to as the posterior and anterior channels.

A fastener is loaded automatically 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 unit is provided sterile and is a single use device.

Indications for Use:

The EndoGastric Solutions EsophyX2 System with SerosaFuse Fastener 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.

Comparison to Predicate Device:

The design of the EndoGastric Solutions EsophyX2 System with SerosaFuse Fastener is essentially the same device with moderate design modifications to make the device easier to use, reduce cost of goods and improve manufacturability. They are devices designed to reach the desired location under endoscopic visualization, grasp tissue in some fashion and place sutures/fasteners in a desired location. The product is re-loadable for repeat fastener placement. The products share common features such as a sterile, stainless steel needle called a stylet, housed a fastener delivery tube. Both devices use the same mechanical mechanism to deliver a fastener through soft tissue by manually actuating the needle with a handle/knob mechanism. The devices are packaged sterile and are for single patient use.
Further, the EndoGastric Solutions EsophyX2 System with SerosaFuse Fastener and the predicate device have the same intended use, which is to place fasteners/sutures/clips to approximate soft tissue under endoscopic visualization. Verification testing provided proof the modifications met the design specifications and biocompatibility testing provided evidence there were no changes to that safety aspect of the device.

Summary:

Based upon the intended use, product technical information, performance and biocompatibility information provided in this pre-market notification, the EndoGastric Solutions EsophyX2 system with SerosaFuse Fastener is substantially equivalent to the currently marketed predicate device in terms of design, performance and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Mr. Steven J. Hoffman
Director, Regulatory Affairs & Quality Assurance
EndoGastric Solutions, Inc.
8210 154th Avenue, N.E.
REDMOND WA 98052

NOV - 6 2009

Re: K092400
Trade/Device Name: EndoGastric Solutions EsophyX2 Device with SerosaFuse Fastener and Accessories
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODE
Dated: October 6, 2009
Received: October 7, 2009

Dear Mr. 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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K092400

7.1 INDICATIONS FOR USE

510(k) Number (if known): TBD

Device Name: EndoGastric Solutions EsophyX2 Device with SerosaFuse Fastener and Accessories

Indications For Use:

The EndoGastric Solutions EsophyX2 Device with SerosaFuse Fastener 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K092400