SECTION 12. 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: K091832

JUL 22 2009

Applicant Information:

Date Prepared:	June 5, 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 StomaphyX® Delivery Device, Fasteners and Accessories
Common Name:	Endoscopic Tissue Approximation Device, Implantable Fastener and Accessories
Classification Name:	Endoscope and Accessories (21 CFR 876.1500, Product Code OCW)

Predicate Devices:

The EndoGastric Solutions StomaphyX Device and Implantable Fasteners is substantially equivalent in intended use and method of operation to a combination of the following predicate device:

K062875 - EndoGastric Solutions StomaphyX Device and Accessories
K073644 - EndoGastric Solutions StomaphyX Device and Accessories

Device Description:

The EndoGastric Solutions StomaphyX Delivery System and Implantable Fasteners consist of an ergonomic, flexible fastener delivery device and sterile polypropylene fastener implants delivered through a fastener cartridge. The unit is provided sterile and is a single use device. The polypropylene fasteners are proprietary and function only with the StomaphyX device.

The device uses vacuum to invaginate tissue through a port into a chamber and fastens it using H-shaped polypropylene fasteners.
The fastener delivery subsystem is comprised of 3 elements: stylet, pusher, and internal lumens. The three elements run the length of the device, inside the outer shaft. The pusher is a hollow tube that rides over the length of the stylet. The stylet provides a "pilot" hole for the fastener to pass through the tissue and both ride inside the lumen. The stylet is a wire three-faceted, sharpened tip at the distal end to pierce tissue.

A fastener is loaded for deployment by depressing the lever on the removable, fastener cartridge located at the proximal end of the device. This action automatically snaps the fastener onto the stylet. When the pusher tube is pushed by the operator, the stylet carries the fastener down the lumen which runs from the proximal handle assembly to the distal tissue port where it will eventually be deployed into the tissue.

Indications for Use:

The EndoGastric Solutions StomaphyX® system with SerosaFuse® Fastener is intended for transoral tissue approximation, ligation and full-thickness plications within the G.I. tract.

Comparison to Predicate Device:

The design of the EndoGastric Solutions StomaphyX System with SerosaFuse® Fastener is identical to the predicate listed in that they are devices designed to reach the desired suture location under endoscopic visualization, grasp tissue in some fashion and place sutures/fasteners in a desired location. The products are re-loadable for repeat fastener/suture placement. The products share common features such as a sterile, stainless steel needle called a stylet, housed in a fastener loading unit. They deliver a fastener/suture 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 StomaphyX 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.

Summary:

Based upon the intended use, product technical information, performance and biocompatibility information provided in this pre-market notification, the EndoGastric Solutions StomaphyX 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
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 22 2009

Re: K091832
Trade/Device Name: EndoGastric Solutions StomaphyX Device with SerosaFuse Fastener
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated: June 18, 2009
Received: June 22, 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

7.1 Indications for Use

510(k) Number (if known): K091832

Device Name: EndoGastric Solutions StomaphyX Device with SerosaFuse Fastener

Indications For Use:

The EndoGastric Solutions, StomaphyX System with SerosaFuse Fastener is intended for transoral tissue approximation, ligation and full-thickness plication in the G.I. tract.

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 K091832