JUN 27 2008

3. 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: TBD K073644

Applicant Information:

Date Prepared:	June 23, 2008
Name:	EndoGastric Solutions, Inc.
Address:	8210 154th Avenue N.E. Redmond, WA 98052 Phone: 425 307 9200 Fax: 425 307 9201
Contact Person:	Ken Perino
Phone Number:	Office: 425-307-9233 / Cell 206-963-8334
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
Classification Name:	Endoscope and Accessories 78 OCW / 21 CFR 876.1500

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 devices:

K071651 – EndoGastric Solutions EsophyX System with SerosaFuse Fastener and accessories
K062875 – EndoGastric Solutions StomaphyX Device and accessories

Device Description:

The EndoGastric Solutions StomaphyX™ Delivery Device and Implantable Fasteners consist of an ergonomic, flexible fastener delivery device and sterile polypropylene fastener implants. 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 fasten it using H shaped polypropylene fasteners. The fastener delivery subsystem is comprised of 3 elements: stylet, pusher, and internal lumens. They run the length of the device, the pusher being a hollow tube that rides over the length of the stylet, both riding in the lumen. The stylet is sharp at the distal tip to pierce tissue. The fastener is loaded by snapping it onto the stylet in the loading port of the handle. When 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.

Intended Use:

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

Comparison to Predicate Device(s):

The design of the EndoGastric Solutions StomaphyX™ system with SerosaFuse™ Fastener is similar to the predicates listed in that they are all devices designed to reach the desired suture location under endoscopic visualization, grasp tissue in some fashion and place sutures/clips in a desired location. All products are re-loadable for repeat fastener/suture/clip placement. The products all share common features such as a sterile, stainless steel needle (called a stylet in the StomaphyX device) housed in a suture loading unit. They all deliver fastener/suture/clips through soft tissue by manually actuating the needle with a handle mechanism. All devices are packaged sterile and are for single patient use. Further, the EndoGastric Solutions StomaphyX™ system with SerosaFuse™ Fastener and the predicate devices have the same or similar intended use, which is to place sutures/clips (fasteners) to approximate soft tissue under endoscopic visualization.

Summary:

Based upon the intended use, descriptive information, and performance evaluation provided in this pre-market notification, the EndoGastric Solutions StomaphyX™ system with SerosaFuse™ Fastener has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

Mr. Ken Perino
Director Regulatory Affairs
EndoGastric Solutions, Inc.
8210 154th Avenue N.E.
REDMOND WA 98052

Re: K073644
Trade/Device Name: EndoGastric Solutions StomaphyX Delivery Device, Fasteners and Accessories
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated: June 17, 2008
Received: June 24, 2008

Dear Mr. Perino:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073644

Device Name: **EndoGastric Solutions StomaphyX Device and Accessories**

Indications For Use:

The EndoGastric Solutions StomaphyX™ system with SerosaFuse™ Fastener is intended for 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 K073644