

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: K071651

SEP 14 2007

Applicant Information:

Date Prepared: June 14, 2007
Date Revised: September 12, 2007

Name: EndoGastric Solutions, Inc.
Address: 8210 154th Avenue N.E.
Redmond, WA 98052
Phone: 425 307 9200
Fax: 425 307 9201

Contact Person: Michael A. Daniel
Phone Number: Office: 925-254-5228 / Cell 415-407-0223
Facsimile Number: (925) 254-5187

Device Information:

Classification: Class II
Trade Name: EndoGastric Solutions (EGS) EsophyXTM System with SerosaFuseTM
Fastener and accessories
Common Name: Endoscopic tissue approximation/plication system
Classification Name: Nonabsorbable Polypropylene Surgical Suture GAW / 21 CFR 878.5010
Endoscopic Suture/Plication System, (GERD) ODE / 21 CFR 876.1500
Endoscopic Tissue Approximation Device OCW / 21 CFR 876.1500

Predicate Devices:

The EndoGastric Solutions (EGS) EsophyXTM System with SerosaFuseTM Fastener and accessories is substantially equivalent in intended use and method of operation to a combination of the following predicate devices:

| | |
|--|-------------------|
| NDO Surgical Endoscopic Plication System | K023234 |
| Bard Endoscope Suturing System / Bard EndoCinch | K994290 / K003956 |
| EGS StomaphyX TM endoluminal fastener and delivery system | K062875 |

Device Description:

The EndoGastric Solutions SerosaFuse™ implantable fasteners, and associated EsophyX delivery device and accessories consist of sterile polypropylene fastener implants and an ergonomic, flexible fastener delivery device. The fasteners and delivery devices are provided sterile and are for single use. The polypropylene fasteners are proprietary and function only with the EGS delivery devices. The delivery devices use either a stainless steel helix or suction to grasp tissue and fasten it using the SerosaFuse polypropylene fasteners. The fastener delivery subsystem comprises 3 elements: stylet, pusher, and a lumen. 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 (EGS) EsophyX™ System with SerosaFuse™ Fastener is indicated for use in endoluminal, 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 $\leq 2\text{cm}$ in size in patients with symptomatic chronic gastroesophageal reflux disease.

Comparison to Predicate Device(s):

The design of the EndoGastric Solutions SerosaFuse™ implantable fasteners, associated delivery devices and accessories is similar to the predicates listed in that they are all devices designed to reach the desired suture location under endoscopic visualization, grasp tissue 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 EGS delivery devices) housed in a suture loading unit (the delivery device). 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 SerosaFuse™ implantable fasteners, associated delivery devices and accessories and the predicate devices have the same or similar intended use.

Summary:

Based upon the intended use, descriptive information, and performance evaluation provided in this pre-market notification, the EndoGastric Solutions SerosaFuse™ implantable fasteners, associated delivery devices and accessories have been shown to be substantially equivalent to currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 14 2007

Mr. Michael A. Daniel
Vice President, Regulatory and Clinical Affairs
EndoGastric Solutions™, Inc.
8210 154th Avenue, N.E.
REDMOND WA 98052

Re: K071651

Trade/Device Name: EsophyX™ System with EGS SerosaFuse™ Fasteners and accessories
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODE
Dated: June 15, 2007
Received: June 18, 2007

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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.



Protecting and Promoting Public Health

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.

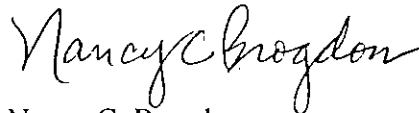
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|----------------|---------------------------------|--------------|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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
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): K071651

Device Name: EndoGastric Solutions (EGS) EsophyX™ System with SerosaFuse™ Fastener and accessories

Indications For Use:

The EndoGastric Solutions (EGS) EsophyX™ System with SerosaFuse™ Fastener is indicated for use in endoluminal, 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 ≤ 2 cm in size in patients with symptomatic chronic gastroesophageal reflux disease.

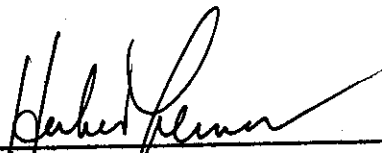
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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
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