510(k) Summary of Safety and Effectiveness

SUBMITTER:	United States Surgical, a division of Tyco Healthcare Group LP 150 Glover Avenue Norwalk, CT 06856 Tel. No.: (203) 845-1000
	MAY 31 2006
CONTACT PERSON:	Frank Gianelli Senior Associate, Regulatory Affairs
DATE PREPARED:	April 17, 2006
TRADE/PROPRIETARY NAME:	Auto Suture™ ENDO GIA™ Stapler
COMMON/USUAL NAME:	Staple, Implantable
CLASSIFICATION NAME:	Staple, Implantable
PREDICATE DEVICE(S):	Auto Suture™ ENDO GIA™ Stapler
DEVICE DESCRIPTION:	The Auto Suture™ ENDO GIA™ Stapler places two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows. The size of the staples is determined by the selection of the 2.0 mm, 2.5 mm, 3.5 mm or 4.8 mm single-use loading unit (SULU). The ENDO GIA™ Stapler will accommodate any of the single-use loading units that are available in 30 mm, 45 mm and 60 mm sizes.
INTENDED USE:	The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.
TECHNOLOGICAL CHARACTERISTICS:	The Auto Suture™ ENDO GIA™ Stapler is identical to the predicate device. The only change is the inclusion of a specific indication concerning the device's use on liver tissue as a subset of the general indication for the Auto Suture™ ENDO GIA™ Stapler.
MATERIALS:	All components of the Auto Suture™ ENDO GIA™ Stapler are comprised of materials which are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	In-vivo animal tests were performed to support the inclusion of a specific indication as a subset of the general indication for the Auto Suture™ ENDO GIA™ Stapler. A clinical literature search was also performed to demonstrate and support the clinical application of the device for the resection and transection of liver.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 1 2006

United States Surgical
% Mr. Frank Gianelli
Senior Associate, Regulatory Affairs
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K061095
Trade/Device Name: Auto Suture™ ENDO GIA™ Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW & GAG
Dated: April 17, 2006
Received: April 19, 2006

Dear Mr. Gianelli:

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.

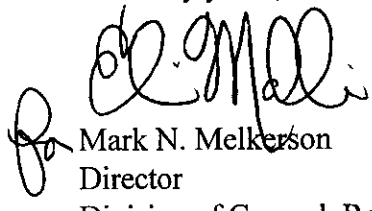
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K061095

Device Name: **Auto Suture™ ENDO GIA™ Stapler**

Indications For Use:

The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 General, Restorative, and Neurological Devices

510(k) Number K061095