 K080898

510(k) Summary of Safety and Effectiveness

SUBMITTER:	Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien) 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-6060
CONTACT PERSON:	Sharon Alexander Senior Associate, Regulatory Affairs
DATE PREPARED:	March 28, 2008
TRADE/PROPRIETARY NAME:	Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units with Staple Line Reinforcement
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staple
CLASSIFICATION NAME:	Staple, Implantable
PREDICATE DEVICE(S):	Autosuture™ ENDO GIA™ Stapler (K061095) Monofilament BIOSYN™ Suture (K000037) Gore SEAMGUARD® Bioabsorbable Staple Line Reinforcement (K043056) Synovis Peri-Strips® Staple Line Reinforcement (K040119)
DEVICE DESCRIPTION:	The Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units with Staple Line Reinforcement place 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 3.5 mm or 4.8 mm Single Use Loading Unit (SULU). The ENDO GIA™ UNIVERSAL Single Use Loading Units (SULUs) with Staple Line Reinforcement are only available in the straight and articulating 45 mm and 60 mm length cartridges with the 3.5 mm or 4.8 mm staples. The staple line reinforcement material is a synthetic absorbable film prepared from synthetic polyester composed of glycolide, dioxanone, and trimethylene carbonate. The staple line reinforcement material is supplied on each SULU undyed (natural) and is secured to the anvil and cartridge with BIOSYN™ synthetic absorbable suture. Studies indicate that the staple line reinforcement material can be expected to retain measurable mechanical strength through 14 days and absorption should be complete between 90 and 110 days.
INTENDED USE:	The Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units with Staple Line Reinforcement have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

MAY - 5 2008

TECHNOLOGICAL CHARACTERISTICS:	The Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units with Staple Line Reinforcement are substantially equivalent to the predicate devices with regard to the stapling and staple line reinforcement technologies.
MATERIALS:	All components of the Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units with Staple Line Reinforcement are comprised of materials which are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	Performance evaluations were completed to verify that the Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units with Staple Line Reinforcement are safe and effective and perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2008

Tyco Healthcare Group, LP
% Ms. Sharon Alexander
Senior Associate, Regulatory
Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K080898
Trade/Device Name: Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units with Staple Line Reinforcement
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: March 28, 2008
Received: March 31, 2008

Dear Ms. Alexander:

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 (240) 276-0115. 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,

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): K080898

Device Name: **Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units with Staple Line Reinforcement**

Indications For Use:

The Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units with Staple Line Reinforcement have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K080898