510(k) Summary of Safety and Effectiveness

OCT 25 2011

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) 492-5352
CONTACT PERSON:	Frank Gianelli Senior Associate, Regulatory Affairs
DATE PREPARED:	October 19, 2011
TRADE/PROPRIETARY NAME:	Endo GIA™ Staplers DST Series™ GIA™ Staplers DST Series™ TA™ Staplers
COMMON/USUAL NAME:	Staple, Implantable
CLASSIFICATION NAME:	Staple, Implantable a. Panel no and product code: 79-GDW b. Regulation no: 21 CFR 878.4750
PREDICATE DEVICE(S):	Endo GIA™ Staplers (K061095, K083519, K093410, K101444, K103263, K102291, K080898) DST Series™ GIA™ Staplers (K032696) DST Series™ TA™ Staplers (K032696) ENDOPATH Linear Cutters and Staplers (K070887) Echelon Linear Cutters and Staplers (K070887
DEVICE DESCRIPTION:	The 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 appropriate single use reload that is available in 30, 45 and 60 mm lengths as well as being available with optional Duet TRS™ staple line reinforcement material and optional curved-tip anvil for reloads with Tri-Staple™ Technology: • 2.0 mm staple size single use reload (gray cartridge) • 2.5 mm staple size single use reload (white cartridge • 3.5 mm staple size single use reload (blue cartridge) • 4.8 mm staple size single use reload (green cartridge) • 2.0, 2.5, 3.0 mm staple size single use reload with Tri-Staple™ Technology (tan cartridge) • 3.0, 3.5, 4.0 mm staple size single use reload with Tri-Staple™ Technology (purple cartridge) • 4.0, 4.5, 5.0 mm staple size single use reload with Tri-Staple™ Technology (black cartridge) The Endo GIA™ Single Use Radial Reload with Tri-Staple™ Technology 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 appropriate single use reload that is available in a 60 mm length only: • 3.0, 3.5, 4.0 mm staple size single use radial reload with Tri-Staple™ Technology (purple cartridge)

The DST Series™ GIA™ Stapler place two double staggered rows of titanium staples and simultaneously divides the tissue between the two double rows. The size of the staples is determined by the selection of the appropriate single use reload that is available in 60, 80 and 100 mm lengths:

- 2.5 mm staple size single use reload (white cartridge) (60, 80, and 100 mm lengths)
- 3.5 mm staple size single use reload (blue cartridge) (80 and 100 mm lengths only
- 4.8 mm staple size single use reload (green cartridge) (80 and 100 mm lengths only)

The DST Series™ SGIA™ Knifeless Stapler places two double staggered rows of titanium staples. The size of the staples is determined by the selection of a 2.5 mm staple size single use reload available in a 60 mm length only.

The DST Series™ TA™ Stapler places a double staggered row of titanium staples. The size of the staples is determined by the selection of the appropriate single use reload that is available in 30, 45, 60 and 90 mm lengths:

- 2.5 mm staple size single use reload (white cartridge) (30, 45, 60 and 90 mm lengths)
- 3.5 mm staple size single use reload (blue cartridge) (45, 60 and 90 mm lengths only
- 4.8 mm staple size single use reload (green cartridge) (45, 60 and 90 mm lengths only)

INTENDED USE:

Endo GIA™ Staplers:
The Endo GIA™ Staplers 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 **and for transection and resection of pancreas.**

Endo GIA™ Radial Reload with Tri-Staple™ Technology:
The Endo GIA™ Radial Reload with Tri-Staple™ Technology has application in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures **and for transection and resection of pancreas**.

DST Series™ GIA™ Staplers:
The DST Series™ GIA™ Staplers and the DST Series™ SGIA™ Knifeless Stapler have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis. The SGIA™ Knifeless stapler may be used for occlusion of the left atrial appendage in open procedures. **They may be used for transection and resection of pancreas**.

DST Series™ TA™ Staplers:
The Auto Suture™ TA™ Reloadable staplers have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection or transection of tissue and creation of anastomosis, including occlusion of the left atrial appendage in open procedures. **They may be used for transection and resection of pancreas.**

TECHNOLOGICAL CHARACTERISTICS:

The Endo GIA™ Staplers, DST Series™ GIA™ Staplers and DST Series™ TA™ Staplers are each identical to their predicate device. The only change is the inclusion of a specific indication concerning each device's use for the **transection and resection of pancreas** as a subset of the general indication for each of these devices.

MATERIALS:

All components of the Endo GIA™ Staplers, DST Series™ GIA™ Staplers and DST Series™ TA™ Staplers are comprised of materials, which are in accordance with ISO Standard 10993-1.

PERFORMANCE DATA:

A clinical literature review was performed to demonstrate and support the clinical application of the Endo GIA™ Staplers, DST Series™ GIA™ Staplers and DST Series™ TA™ Staplers for transection and resection of pancreas.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 25 2011

Covidien
% Mr. Frank Gianelli
Senior Associate, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K111825
Trade/Device Name: Endo GIA™ Stapler, DST Series™ GIA™ Stapler and DST Series™ TA™ Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: September 29, 2011
Received: September 30, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications For Use

510(k) Number (if known): K111825

Device Name: **Endo GIA™ Stapler, DST Series™ GIA™ Stapler and DST Series™ TA™ Stapler**

Indications For Use:

Endo GIA™ Staplers:

The following indications are applicable to the Endo GIA™ Ultra Universal Stapler with Endo GIA™ Reloads with Tri-Staple™ Technology including Curved Tip Reloads:

The Endo GIA™ Ultra Universal Staplers 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 **and for transection and resection of pancreas.**
The Endo GIA™ Ultra Universal Staplers when used with the Endo GIA™ Curved-Tip Reloads can be used to blunt dissect or separate target tissue from other certain tissue.

The following indications are applicable to the Endo GIA™ Ultra Universal Stapler with Duet TRS™ Reloads with Tri-Staple™ Technology including Duet TRS™ Curved Tip Reloads:

The Endo GIA™ Ultra Universal Staplers with Duet TRS™ Reloads with Tri-Staple™ Technology 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 **and for transection and resection of pancreas.**
The Endo GIA™ Ultra Universal Staplers when used with the Duet TRS™ Curved-Tip Reloads can be used to blunt dissect or separate target tissue from other certain tissue.

The following indications are applicable to the Endo GIA™ Ultra Universal Stapler with Radial Reload with Tri-Staple™ Technology:

The Endo GIA™ Radial Reload with Tri-Staple™ Technology has application in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection.
It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures **and for transection and resection of pancreas.**

The following indications are applicable to the Endo GIA™ Universal Stapler with Endo GIA™ Straight and Roticulator™ SULUs:

The Endo GIA™ Universal Staplers 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 **and for transection and resection of pancreas.**

The following indications are applicable to the Endo GIA™ Universal Stapler with Duet TRS™ Reloads:

The Endo GIA™ Ultra Universal Staplers with Duet TRS™ Reloads 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 **and for transection and resection of pancreas.**

DST Series™ GIA™:

The Auto Suture™ GIA™ Reloadable Staplers and the SGIA™ Knifeless Stapler have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis. The SGIA™ Knifeless stapler may be used for occlusion of the left atrial appendage in open procedures. **They may be used for transection and resection of pancreas.**

DST Series™ TA™:

The Auto Suture™ TA™ Reloadable staplers have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection or transection of tissue and creation of anastomosis, including occlusion of the left atrial appendage in open procedures. **They may be used for transection and resection of pancreas.**

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)

Emil Keith

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111825