K120258

510(k) Summary of Safety and Effectiveness

FEB 2 9 2012

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:	Jennifer Brennan Manager, Regulatory Affairs
DATE PREPARED:	January 20, 2012
TRADE/PROPRIETARY NAME:	Duet TRS™ Reloads, Duet TRS™ Reloads with Tri-Staple™ Technology Endo GIA™ Universal and Ultra Universal Staplers
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staples
CLASSIFICATION NAME:	Staples, Implantable
PREDICATE DEVICE(S):	Duet TRS Reloads (K080898, K111825) Duet TRS™ Reloads with Tri-Staple™ Technology (K103263, K111825) Endo GIA™ Universal and Ultra Universal Staplers (K111825)
DEVICE DESCRIPTION:	The Duet TRS™ Reloads when used with Endo GIA™ Staplers place two, triple-staggered rows of titanium staples along with two layers of absorbable tissue reinforcement material (one layer on cartridge side and one layer on anvil side) and simultaneously divides the tissue and reinforcement material between the two, triple-staggered staple rows. The Duet TRS™ Reloads with Tri-Staple™ Technology when used with Endo GIA™ Staplers places two, triple-staggered rows of titanium staples along with two layers of absorbable tissue reinforcement material (one layer on cartridge side and one layer on anvil side) and simultaneously divides the tissue and reinforcement material between the two, triple-staggered staple rows. 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 supplied on each Reload is undyed (natural) and secured to the anvil and cartridge with BIOSYN™ synthetic absorbable suture.

The Endo GIA™ Universal and Ultra Universal Staplers (K111825) with associated staple cartridge reloads are articulating, disposable surgical staplers that simultaneously transect and staple various types of internal tissues. Each can be used in both endoscopic and open surgical procedures, is available in multiple sizes, is for endoscopic procedures and can be introduced and used through appropriately sized trocar endoscopic access cannulae.

INTENDED USE:

The Endo GIA™ Universal Staplers with Duet TRS™ reloads have applications in abdominal, gynecologic and pediatric surgery for resection, transection and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas

The Duet TRS™ Reloads with Tri-Staple™ Technology have applications in abdominal, gynecologic and pediatric surgery for resection, transection and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas

TECHNOLOGICAL CHARACTERISTICS:

Duet TRS™ Reloads and the Duet TRS™ Reloads with Tri-Staple™ Technology and the Endo GIA™ Staplers Universal and Ultra Universal are identical to the predicate devices.

MATERIALS:

All components of the Duet TRS™ Reloads and the Duet TRS™ Reload with Tri-Staple™ Technology and the Endo GIA™ Staplers (Universal and Ultra Universal) are comprised of materials that are in accordance with ISO Standard 10993-1.

PERFORMANCE DATA:

There have been no changes to the design of the Duet TRS™ Reloads, the Duet TRS™ Reloads with Tri-Staple™ Technology, or the Endo GIA™ Universal and Ultra Universal Staplers Performance evaluations were not required to support this labeling modification.

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

Covidien
% Ms. Jennifer Brennan
Manager, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

FEB 29 2012

Re: K120258
Trade/Device Name: Duet TRS™ Reloads
Duet TRS™ Reloads with Tri-Staple™ Technology
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: January 25, 2012
Received: January 27, 2012

Dear Ms. Brennan:

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,

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):

Device Name: **Duet TRS™ Reloads**
Duet TRS™ Reloads with Tri-Staple™ Technology

Indications For Use:

The Endo GIA™ Universal Staplers with Duet TRS™ reloads have applications in abdominal, gynecologic and pediatric surgery for resection, transection and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas

The Duet TRS™ Reloads with Tri-Staple™ Technology have applications in abdominal, gynecologic and pediatric surgery for resection, transection and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas

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)

David Krueger for MKM

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

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