510(k) Summary

JAN 2 2 2014

This 510(k) summary information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.98.

Submitter Information

Name:	Covidien llc
Address:	15 Hampshire Street Mansfield, MA 02048
Establishment Registration:	1282497
Name of contact person:	Jose Marquez Regulatory Affairs Manager Covidien 15 Hampshire Street Mansfield, MA 02048 USA Phone: (508) 452-4160
Date prepared:	January 22, 2014
Trade or proprietary name:	Endo GIA™ Reinforced Reload with Tri-Staple™ Technology
Common or usual name: **Classification name:** **Classification panel:**	Surgical Stapler with Implantable Staple Staple, Implantable General and Plastic Surgery (79)
Regulation:	21 CFR 878.4750
Product Code(s):	GDW, ORQ
Legally marketed devices to which equivalence is claimed:	• Endo GIA™ Stapler (K111825) • NEOVEIL™ Reinforcement Staple Line Material (K130997)
Reason for 510(k) submission:	To obtain market clearance for the Endo GIA™ Reinforced Reload with Tri-Staple™ Technology.
Device description:	The Endo GIA™ Reinforced Reload with Tri-Staple™ Technology places two, triple-staggered rows of titanium staples with a reinforcement material and simultaneously divides the

tissue and the reinforcement material between the two, triple-staggered rows. The absorbable staple line reinforcement material, comprised of a synthetic polyester composed of pure glycolide, will be secured to the anvil and cartridge sides of the reload with four synthetic absorbable sutures. The size of the staples is determined by the selection of the 3.0-4.0 mm or 4.0-5.0 mm Reload. The Endo GIA™ Reinforced Reload with Tri-Staple™ Technology is only available in the articulating 45 mm and 60 mm length cartridges with the 3.0-4.0 mm or 4.0-5.0 mm staples, respectively.

Intended use of the device:

Endo GIA™ reinforced reload with Tri-Staple™ Technology preloaded with polyglycolic acid staple line reinforcement has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection of tissue 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.

Summary comparing the technological characteristics of the subject and predicate devices:

The Endo GIA™ Reinforced Reload with Tri-Staple™ Technology is substantially equivalent to the predicate devices with regard to stapling and staple line reinforcement technologies.

Materials:

All components of the Endo GIA™ Reinforced Reload with Tri-Staple™ Technology are comprised of materials which are in accordance with ISO Standard 10993-1.

Performance Data:

Bench and animal performance evaluations were completed to verify that the Endo GIA™ Reinforced Reload with Tri-Staple™ Technology are safe and effective and perform as intended.

The tests performed to show substantial equivalence of the Endo GIA™ Reinforced Reload with Tri-Staple™ Technology to the predicate device are as follows:

- In Vitro
  - Insertion/removal force
  - Firing force
  - Retraction force
  - Staple formation
  - iDrive Ultra testing
  - Tyvek Pull apart
  - Sequential firings
  - Perpendicular firings
  - L-shaped firings
- In Vivo
  - Atraumatic reload

- Free bleed time
- Air leaks

- Burst
- Additional firings

- Biocompatibility

Conclusion:

The results of the tests performed demonstrate that the subject device, Endo GIA™ Reinforced Reload with Tri-Staple™ Technology, is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 22, 2014

Covidien llc
Mr. Jose Marquez
Regulatory Affairs Manager
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K133938
Trade/Device Name: Endo GIA™ Reinforced Reload with Tri-Staple™ Technology
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, ORQ
Dated: December 20, 2013
Received: December 23, 2013

Dear Mr. Marquez:

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 contact 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. 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133938

Device Name
Endo GIA™ Reinforced Reload with Tri-Staple™ Technology

Indications for Use *(Describe)*

Endo GIA™ reinforced reload with Tri-Staple™ Technology preloaded with polyglycolic acid staple line reinforcement has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection of tissue 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S