February 20, 2018

Covidien
Ms. Rebecca Magnanimo
RA Product Specialist
Regulatory Affairs
60 Middletown Ave.
North Haven, Connecticut 06473

Re: K173270
Trade/Device Name: Tri-Staple 2.0 Reinforced Reload
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW OXC
Dated: November 8, 2017
Received: November 20, 2017

Dear Ms. Magnanimo:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173270

Device Name
Tri-Staple 2.0 Reinforced Reload

Indications for Use *(Describe)*
The Tri-Staple 2.0 Reinforced Reload 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510 (k) Number:	K173270
SUBMITTER:	Covidien llc 60 Middletown Avenue North Haven, CT 06473 USA
ESTABLISHMENT REGISTRATION:	1219930
CONTACT PERSON:	Rebecca Magnanimo Regulatory Affairs Product Specialist Covidien llc Phone: (203) 492-6479 Fax: (203) 492-5029 e-mail: Rebecca.a.magnanimo@medtronic.com
DATE:	February 16, 2018
PRODUCT CODE: REGULATION NUMBER:	GDW, OXC 21 CFR 878.4750, 878.3300
TRADE/PROPRIETARY NAME:	Tri-Staple™ 2.0 Reinforced Reload
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staples
CLASSIFICATION NAME:	Staple, Implantable
PREDICATE DEVICE:	Endo GIA™ Reinforced Reload with Tri-Staple Technology (K133938)
DEVICE DESCRIPTION:	The Tri-Staple™ 2.0 reinforced reload places two triple-staggered rows of titanium staples and two layers of absorbable reinforcement material on either side of the cut line. 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. As the staples are deployed, the tissue and staple line reinforcement material are simultaneously divided. The Tri-Staple™ 2.0 reinforced reload is available in articulating 45 mm and 60 mm lengths. The size of the staples is determined by the selection of the 3.0-4.0mm or 4.0-5.0mm reload. The Tri-Staple™ 2.0 reinforced reload will contain an intelligence chip. The intelligence chip will have the ability to communicate with Covidien™ powered stapling handles that have a compatible communications interface.
INTENDED USE	Tri-Staple™ 2.0 Reinforced Reloads are preloaded with polyglycolic acid staple line reinforcement and have 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 Tri-Staple™ 2.0 Reinforced Reload is substantially equivalent to the predicate devices with regard to stapling and staple line reinforcement material composition. The change from the predicate device to the proposed is a change in manufacturer of the reinforcement material.

Materials:

All components of the Tri-Staple™ 2.0 Reinforced Reload 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 Tri-Staple™ 2.0 Reinforced Reload is safe and effective and perform as intended.

The tests performed to show substantial equivalence of the Tri-Staple™ 2.0 Reinforced Reload (proposed) to the predicate device are as follows:

<u>Bench Testing:</u>
In-vitro testing that supports the intended use of the device includes:

- Insertion/removal force
- Firing Force
- Retraction Force
- Staple Formation
- Sequential Firings
- Perpendicular Firings
- L-Shaped Firings

<u>In-vivo (Acute) Testing:</u>
Acute In-vivo testing that supports the intended use of the device includes

- Atraumatic Testing
- Blood Loss Evaluation (hemostasis)
- Air Leak Evaluation
- Analysis of Staple line burst pressure
- Staple formation

<u>In-vivo (Survival) Testing:</u>

- Abdominal
- Thoracic
- Persistance
- Strength loss

Usability Testing: Testing was performed in accordance with IEC 62366-1.

Biocompatibility Testing: Verification device materials are in agreement with ISO 10993-1 for their intended patient contact profile.

Electrical Safety testing was assessed per IEC 60601-1.

EMC/EMI testing was assessed per IEC 60601-1-2.

CONCLUSION: The results of testing demonstrate that the modified Tri-Staple™ 2.0 Reinforced Reload is substantially equivalent to the legally marketed Endo GIA™ Reinforced Reload with Tri-Staple Technology (K133938).