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

December 5, 2016

Covidien LLC
Ms. Rebecca Brewer
Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K163098
Trade/Device Name: Tri-Staple™ 2.0 Intelligent Cartridges
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: November 4, 2016
Received: November 7, 2016

Dear Ms. Brewer:

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163098

Device Name
Tri-Staple™ 2.0 Intelligent Cartridge

Indications for Use *(Describe)*
The Signia™ intelligent loading units and Tri-Staple™ 2.0 intelligent cartridges 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (8/14) Page 1 of 1

510(k) Summary of Safety and Effectiveness

Date Prepared:
November 4, 2016

Submitter:
Covidien
60 Middletown Avenue
North Haven, CT 06473

Contact:
Rebecca Brewer
Regulatory Affairs Specialist
Telephone: (203) 492-5299
Fax: (203) 492-5029
Email: rebecca.j.brewer@medtronic.com

Name of Device:

Trade/Proprietary Name:	Tri-Staple™ 2.0 Intelligent Cartridges
Common Name:	Surgical Stapler with Implantable Staples
Classification Name:	Staples, Implantable a. Panel no and product code: 79 GDW b. Regulation no: 21 CFR 878.4750

Predicate Device:

Trade/Proprietary Name:	Endo GIA™ Reloads with Tri-Staple™ Technology, Signia™ Loading Units with Tri-Staple™ 2.0 cartridges and Signia™ Stapler
Common Name:	Surgical Stapler with Implantable Staples
Classification Name:	Staples, Implantable, (79 GDW, 21 CFR 878.4750)
510(k) Number:	K111825, K151163, K160176
Manufacturer:	Covidien

Device Description:
The Signia™ Intelligent Loading Units and Tri-Staple™ 2.0 Intelligent Cartridges place staggered rows of titanium staples and simultaneously divides the tissue so that three staggered rows of staples are placed on either side of the cut line. The size of the staples is determined by the selection of the following single use Tri-Staple™ 2.0 Intelligent Cartridges:

Tri-Staple™ 2.0 Intelligent Cartridge, Extra Thin/Vascular:

- Cartridge color: Gray - three rows of 2.0 mm titanium staples on either side of the cut line.

Tri-Staple™ 2.0 Intelligent Cartridge, Vascular/Thin:

- Cartridge color: White - three rows of 2.5 mm titanium staples on either side of the cut line.

The Tri-Staple™ 2.0 Intelligent Cartridge is available in 45 mm and 60 mm lengths. Tri-Staple™ 2.0 Intelligent Cartridges are able to be loaded into the Signia™ Intelligent Loading Unit of corresponding length by the User. Signia™ Intelligent Loading Units may be used up to twelve times in the same procedure. Signia™ Intelligent Loading Units with Tri-Staple™ 2.0 Intelligent Cartridges, similar to the predicate devices, are compatible with Covidien's GIA™ Universal staplers, Endo GIA™ Universal staplers, Endo GIA™ Ultra Universal staplers, iDrive™ Ultra powered staplers with Endo GIA™ adapters and Signia™ staplers with Signia™ linear adapters.

In the recently cleared Signia™ Staplers and Signia™ Linear Adapters (K160176), the communication of the Tri-Staple™ 2.0 Cartridges and Signia™ Loading Units with the Signia™ Stapler was announced, leading to the addition of the "Intelligent" descriptor in the Trade/Proprietary Name of the devices noted above.

Intended Use:
The Signia™ Intelligent Loading Units and Tri-Staple™ 2.0 Intelligent Cartridges 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.

Note: The Signia™ Intelligent Loading Units with Tri-Staple™ 2.0 Intelligent Cartridges are intended for use with GIA™ Universal staplers, Endo GIA™ Universal staplers, Endo GIA™ Ultra Universal staplers, iDrive™ Ultra powered staplers with Endo GIA™ adapters and Signia™ staplers with Signia™ linear adapters and do not carry a separate indication from the stapling devices.

Technological and Performance Characteristics:
Signia™ Intelligent Loading Units with Tri-Staple™ 2.0 Intelligent Cartridges (Gray and White) are substantially equivalent to the predicate Endo GIA™ Gray Articulating Reload ("Gray Reload" from this point forward) and Endo GIA™ AutoSuture™ Universal Articulating Loading Unit ("White Reload" from this point forward), and the Signia™ Loading Units with Tri-Staple™ 2.0 Cartridges ("Purple" and "Tan") in regard to the stapling technologies employed.

Qualitative and quantitative data were obtained and used to compare the Tri-Staple™ 2.0 Gray and White cartridges to the predicate Endo GIA™ Reloads.

All aspects were found to be identical, with the exception of the following characteristics:

1. Construct change:
   Tri-Staple™ 2.0 Intelligent Cartridge, Extra Thin/Vascular:
   - Cartridge color: Gray - three rows of 2.0 mm titanium staples on either side of the cut line.

   Tri-Staple™ 2.0 Intelligent Cartridge, Vascular/Thin:
   - Cartridge color: White - three rows of 2.5 mm titanium staples on either side of the cut line.

2. Material Change
   Addition of an alternate flux material used in the cartridge distal chip assembly.

3. Material Change
   New colorant formulation in material of the gray and white cartridges.

The design differences were found to not affect safety or performance through applicable design verification activities that showed continued conformance to applicable technical design specifications and performance requirements, applicable medical device performance standards, and other nonclinical testing.

Tests performed to evaluate and compare technological and performance characteristics:

1. Bench tests using simulated tissue medium was performed to evaluate the following technological and performance characteristics in order to confirm the safety and efficacy of the Tri-Staple™ 2.0 Gray and White Cartridges for use with Signia™ Loading Units:
   - Staple formation
   - Knife cutting
   - Cartridge insertion/removal forces
   - Trocar Insertion/Removal Force
   - Clamp/Unclamp forces
   - Firing force
   - Lockout force
   - Retraction force
   - iDrive Ultra Powered Firing

- Proximal Chip Communication
- Shield retention Force

2. In vivo and ex vivo tests using canine animal models were performed to evaluate the following performance characteristics
   - Acute hemostasis
   - Acute air leak
   - Burst pressure
   - Staple formation
   - Tissue grasping and trauma

3. Usability Tests

4. Biocompatibility tests in accordance with ISO Standard 10993-1 were performed to confirm that new components of the Tri-Staple™ 2.0 Gray and White Cartridges are comprised of materials that are in accordance with ISO Standard 10993-1 for their intended patient contact profile.

5. Electrical Safety Tests per IEC 60601-1

6. EMC/EMI Tests per IEC 60601-1-2

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion:
Through the comparison of technological and performance characteristics and the results of evaluation testing, the Tri-Staple™ 2.0 Gray and White Cartridges were found to be substantially equivalent to the predicate devices.