DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 29, 2015

Covidien LLC
Mr. Frank Gianelli
Senior Product Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K151163
Trade/Device Name: Signia Loading Units with Tri-Staple™ 2.0 Cartridges
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: April 30, 2015
Received: May 1, 2015

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 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" (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 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 yours,

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)* K151163

Device Name

Signia Loading Units with Tri-Staple™ 2.0 cartridges

Indications for Use *(Describe)*

The Signia Loading Units with Tri-Staple™ 2.0 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 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 of Safety and Effectiveness

Date Prepared:
April 30, 2015

Submitter:
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Name of Device:

Trade/Proprietary Name:	SigniaTM Loading Units with Tri-StapleTM 2.0 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
Common Name:	Surgical Stapler with Implantable Staples
Classification Name:	Staples, Implantable, (79 GDW, 21 CFR 878.4750)
51O(k) Number:	K111825, K083519
Manufacturer:	Covidien

Device Description:
The SigniaTM Loading Units and Tri-StapleTM 2.0 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-StapleTM 2.0 cartridges:

Tri-Staple™ 2.0 cartridge, vascular/medium:

- Tan- three height progressive rows of 2.0 mm, 2.5 mm, 3.0 mm titanium staples on either side of the cut line.

Tri-StapleTM 2.0 cartridge, medium/thick:

- Purple- three height progressive rows of 3.0 mm, 3.5 mm and 4.0 mm titanium staples on either side of the cut line.

The Tri-StapleTM 2.0 Cartridge is available in 45 mm and 60 mm lengths. The SigniaTM Loading Unit is available in articulating 45 mm and 60 mm lengths. Tri-StapleTM 2.0 Cartridges are able to be loaded into the SigniaTM Loading Unit by the User. SigniaTM Loading Units may be used up to twelve times in the same procedure. Signia™ Loading Units with Tri-Staple™ 2.0 Cartridges, similar to the predicate devices, are compatible with Covidien's Endo GIA™ Ultra Universal and Universal manual stapler handles and iDrive™ Ultra powered stapler handle with associated Endo GIA™ Adapter.

Intended Use:
The SigniaT" Loading Units with Tri-StapleT" 2.0 Cartridges have applications in abdominal, gynecologic, pediatric and thoracic 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 transection and resection of pancreas.

Note: The Signia™ Loading Units with Tri-StapleT" 2.0 Cartridges is intended for use with Endo GIATM Stapiers and does not carry a separate indication from the stapling devices.

Technological and Performance Characteristics:
SigniaTM Loading Units with Tri-StapleT• 2.0 Cartridges are substantially equivalent to the predicate Endo GIAT" Reloads with Tri-StapleTM Technology in regard to the stapling technologies employed.

Qualitative and quantitative data were obtained and used to compare the SigniaTM Loading Units with Tri-StapleT" 2.0 cartridges to the predicate Endo GIAT" Reloads with Tri-StapleTM Technology.

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

1. Construct change:
   Two-modular configuration:
   - Single-use, multiple-fire Loading Unit containing the anvil and knife.
     I> Loading Unit can be used up to 12 firings per procedure.
     I> The marketing name of the loading unit is SigniaT•.
   - Single-use, single-fire staple cartridge.
     I> The marketing name of the staple Cartridge is Tri-Staple TM 2.0.

2. Material Change
   Addition of an alternate stainless steel material for the anvil component of the Loading Unit.

3. Material Change
   New colorant formulation in material of the "tan" staple Cartridge.

4. New components and materials
   Due to the construct change, new components are used that are made of materials not used in the predicate Endo GIAT" Reloads with Tri-StapleT" Technology.

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 show the reliability of the Signia™ Loading Units to achieve 12 firings in a single patient procedure:
   - Staple formation
   - Knife cutting
   - Cartridge insertion/removal forces
   - Clamp forces
   - Firing force
   - Loading Unit loading/unloading forces
   - Lockout force
   - Retraction force
   - Articulation Angles
   - Articulation Forces

2. In vivo and ex vivo tests using porcine and canine animal models was performed to evaluate the following performance characteristics
   - Acute hemostasis
   - Acute air leak
   - Burst pressure
   - Staple formation
   - Tissue grasping and trauma
   - Use with staple line reinforcement (buttress) material

3. Usability Tests

4. Biocompatibility tests in accordance with ISO Standard 10993-1 was performed to confirm that all components of the SigniaTM Loading Units and Tri-StapleTM 2.0 Cartridges are comprised of materials that are in accordance with ISO Standard 10993-1 for their intended patient contact profile.

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 Signia'M Loading Units with Tri-Staple'M 2.0 Cartridges were found to be substantially equivalent to the predicate devices.