



Food and Drug Administration  
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Silver Spring, MD 20993-0002

April 26, 2016

Covidien  
Mr. Frank Gianelli  
Sr. Product Specialist Regulatory Affairs  
60 Middletown Avenue  
North Haven, Connecticut 06471

Re: K160176  
Trade/Device Name: Signia Stapler  
Regulation Number: 21 CFR 878.4750  
Regulation Name: Implantable staple  
Regulatory Class: Class II  
Product Code: GDW  
Dated: January 22, 2016  
Received: January 27, 2016

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" (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 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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

**Indications for Use**

510(k) Number (if known)

K160176

Device Name

Signia™ Stapler

*Indications for Use (Describe)*

The Signia™ stapler, when used with Endo GIA™ single-use reloads, Endo GIA™ single-use reloads with Tri-Staple™ Technology, Tri-Staple™ 2.0 single-use reloads and Signia™ loading units with Tri-Staple™ 2.0 single-use cartridges, has applications in abdominal, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature, and biliary structures and for transection and resection of the pancreas.

The Sigma™ stapler, when used with Endo GIA™ curved tip single use reloads or Tri-Staple™ 2.0 curved tip single-use reloads, can be used to blunt dissect or separate target tissue from other certain tissue.

The Signia™ stapler, when used with Endo GIA™ single use Radial Reloads with Tri-Staple™ Technology, has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e., low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of the pancreas.

The Signia™ stapler, when used with Endo GIA™ single use reinforced reloads with Tri-Staple™ Technology preloaded with polyglycolic acid staple line reinforcement or Tri-Staple™ 2.0 single use reinforced reloads 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. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures, and for transection and resection of the 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.

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FORM FDA 3881 (8/14)

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## 510(k) Summary of Safety and Effectiveness

**Date Prepared:**  
January 22, 2016

**Submitter:**  
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**Name of Device:**  
Trade/Proprietary Name: Signia™ Stapler  
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: iDrive™ Ultra Powered Handle with Endo GIA™ Adapter  
Common Name: Surgical Stapler with Implantable Staples  
Classification Name: Staples, Implantable, (79 GDW, 21 CFR 878.4750)  
510(k) Number: K121510  
Manufacturer: Covidien

### Device Description:

The Signia™ Stapler is a battery powered microprocessor controlled surgical stapler that provides push-button powered maneuverability and firing of compatible Covidien stapling reloads. The Signia™ Stapler is composed of the Signia™ Power Handle, Signia™ Power Shell, and Signia™ Linear Adapter. System accessories include the Signia™ Reusable Insertion Guide, Signia™ Manual Retraction Tool, and Signia™ Single Bay Charger.

The User controls the Signia™ Stapler via button presses on the Handle and receives feedback status and other information from the Handle via its OLED Display, LED indicator and audible annunciator. Pushbutton / Toggle switches on the Handle are provided for:

- Stapling activation: Advancing the Firing Rod / Clamping / Unclamping
- Left and Right Articulation
- Clockwise and Counter Clockwise Rotation

When the appropriate buttons are pressed, the Signia™ Stapler software initiates stapling (firing), articulation or rotation operation by turning on the appropriate motor. The motors have built-in encoders which provide shaft position information. The software controls motor speed and position using encoder pulses. Since it is possible to press multiple keys simultaneously, software must be able to process them and take appropriate actions.

The Signia™ Stapler is compatible with Endo GIA™ single-use reloads, Endo GIA™ single-use reloads with Tri-Staple™ Technology, Tri-Staple™ 2.0 single use reloads, and Signia™ loading units with Tri-Staple™ 2.0 single-use cartridges.

The Signia™ Stapler when used with the abovementioned family of Endo GIA™ reloads is a surgical device for stapling and cutting tissues. The Signia™ Stapler is intended to be used by medical professionals qualified in the transportation, preparation, cleaning, sterilization, and use of surgical devices.

**Intended Use:**

The Signia™ Stapler, when used with Endo GIA™ single-use reloads, Endo GIA™ single-use reloads with Tri-Staple™ Technology, Tri-Staple™ 2.0 single-use reloads and Signia™ loading units with Tri-Staple™ 2.0 single-use cartridges, has applications in abdominal, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature, and biliary structures and for transection and resection of the pancreas.

The Signia™ Stapler, when used with Endo GIA™ curved tip single use reloads or Tri-Staple™ 2.0 curved tip single-use reloads, can be used to blunt dissect or separate target tissue from other certain tissue.

The Signia™ Stapler, when used with Endo GIA™ single use Radial Reloads with Tri-Staple™ Technology, has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e., low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of the pancreas.

The Signia™ Stapler, when used with Endo GIA™ single use reinforced reloads with Tri-Staple™ Technology preloaded with polyglycolic acid staple line reinforcement or Tri-Staple™ 2.0 single use reinforced reloads 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. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures, and for transection and resection of the pancreas.

Note: The Signia™ Stapler is intended for use with Endo GIA™ Reloads, Endo GIA™ Reloads with Tri-Staple™ Technology, Signia™ Loading Units with Tri-Staple™ 2.0 cartridges and Tri-Staple™ 2.0 Reloads and does not carry a separate indication from these stapling devices.

**Technological and Performance Characteristics:**

The Signia™ Stapler is substantially equivalent to the predicate iDrive Ultra™ Powered Handle with Endo GIA™ Adapter in regard to the stapling technologies employed.

Qualitative and quantitative data were obtained and used to compare the Signia™ Stapler to the predicate iDrive Ultra™ Powered Handle with Endo GIA™ Adapter.

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. Lifecycle Reliability Tests
2. Cleaning Validation Tests
3. Aseptic Barrier Tests
4. Functional Performance Test – Bench and Animal
5. Usability Tests
6. Biocompatibility tests in accordance with ISO Standard 10993-1

7. Electrical Safety Tests per IEC 60601-1
8. 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 Signia™ Stapler was found to be substantially equivalent to the predicate device.