September 4, 2019

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

Re: K191070
Trade/Device Name: Signia Small Diameter Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: April 19, 2019
Received: April 22, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Cindy Chowdhury
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K191070

Device Name
Signia™ Small Diameter Reloads

Indications for Use *(Describe)*
The Signia™ small diameter gray and white reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection and transection ofvasculature using gray reloads and thin tissue and vasculature using white reloads.

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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510(K) Summary

Date Prepared:
August 28, 2019

Submitter:
Covidien
60 Middletown Avenue
North Haven, CT 06473

Contact:
Frank Gianelli
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Name of Device:
Trade/Proprietary Name: Signia™ Small Diameter Reloads
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 Devices:
Primary:

Trade/Proprietary Name:	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit (Gray and White)
Common Name:	Surgical Stapler with Implantable Staples
Classification Name:	Staples, Implantable, (79 GDW, 21 CFR 878.4750)
510(k) Number:	K111825
Manufacturer:	Covidien

Reference:

Trade/Proprietary Name:	Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and Endopath Echelon™ Vascular White Reload for Advanced Placement Tip
Common Name:	Surgical Stapler with Implantable Staples
Classification Name:	Staples, Implantable, (79 GDW, 21 CFR 878.4750)
510(k) Number:	K141952
Manufacturer:	Ethicon Endo-Surgery Inc.

Device Description:
The Signia™ Small Diameter Reload is an 8mm diameter reload that will be utilized for open and minimally invasive surgical procedures for transection and resection of tissue and specifically, vascular and thin tissue structures.

The reload is the distal shaft and jaws of the stapler system; comprised of a single-use knife, fixed curve tip anvil and stapler cartridge with two (2) rows of staples on either side of the knife blade**.**

The Signia™ Small Diameter Reload features a narrow shaft diameter, narrow end-effector, curved-tip anvil, multi-articulation angles, and delivers two staggered rows of titanium staples on either side of the cut line. These features facilitate device access during surgery in smaller/tighter intercostal spaces, smaller surgical spaces and difficult to reach vessels/vasculature.

The Signia™ Small Diameter Reload places staggered rows of titanium staples and simultaneously divides the tissue so that two 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 single use reload.

The Signia™ small diameter reload is available in multiple configurations with the following features:

- Open Staple Height: 2.0 mm (gray cartridge) and 2.5 mm (white cartridge)
- Cartridge Length: 30 mm and 45 mm
- Anvil Tip: Curved
- Reload Shaft Length: Short (15 cm) and Long (24 cm)
- Reload Diameter (mid-shaft to distal end): 8 mm

The curved tip on the distal-end of the reload can be used to aid in positioning the reload around target tissue/vessels for subsequent firing and placement of staples. The working length of the Signia™ small diameter reload will fit through an 8mm trocar sleeve or larger and is compatible with existing Endo GIA™ handles and Signia™ adapters. The short shaft lengths (15cm) are recommended for use in open or thoracic procedures and are compatible with thoracic trocar sleeves. The long shaft lengths (24 cm) are recommended for use in laparoscopic procedures with 8 mm diameter trocar sleeves. Signia™ small diameter reloads are recommended for use with Covidien compatible short Stapler handles and adapters. Signia™ small diameter reloads contain an intelligence chip. The intelligence chip has the ability to communicate with Covidien powered stapler handles that have a compatible communications interface.

Indications for Use:
The Signia™ small diameter gray and white reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of vasculature using gray reloads and thin tissue and vasculature using white reloads.

Technological and Performance Characteristics:
The subject Signia™ Small Diameter Reloads are substantially equivalent to primary predicate Endo GIA™ Auto Suture™ Universal Articulating Loading Units (Gray and White) and to reference predicate Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and Endopath Echelon™ Vascular White Reload for Advanced Placement Tip in regard to the stapling technologies employed, intended use and similar indications for use.

Specifically, the subject Signia™ Small Diameter Reloads when used with compatible Covidien stapler handles is similar to reference predicate Endo GIA™ Auto Suture™ Universal Articulating Loading Units (Gray and White) also when used with compatible Covidien stapler handles with respect to features such as staple line length, staple size, reload color (Gray, White), multi-articulation angles, and intended tissue type of thin/vascular. The main difference between the subject Signia™ Small Diameter Reloads and primary predicate Endo GIA™ Auto Suture™ Universal Articulating Loading Units (Gray and White) is the Signia™ Small Diameter Reloads deliver two-staggered rows of titanium staples on either side of the cut line rather than three-staggered rows of titanium staples on either side of the cut line as with the primary predicate.

Specifically, the subject Signia™ Small Diameter Reloads when used with compatible Covidien stapler handles is similar to reference predicate Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and Endopath Echelon™ Vascular White Reload for Advanced Placement Tip with respect to features such as narrow shaft diameter, narrow end-effector, curved-tip anvil, multi-articulation angles, and delivering two staggered rows of titanium staples on either side of the cut line. Also, the intended tissue type of thin/vascular is the same for both.

Feature	Proposed Device **Signia™ Small Diameter Reload (Gray and White)**	Primary Predicate Device (K111825) **Endo GIA™ Auto Suture™ Universal Articulating Loading Units (Gray and White)**	Reference Predicate Device (K141952) **Echelon PVS with Echelon Vascular Reload**
Same basic function for reloads - rotation, articulation, clamp, unclamp, firing, retraction, grasping	Yes	Yes	Yes
Indications for use	The Signia™ small diameter gray and white reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of vasculature using gray reloads and thin tissue and vasculature using white reloads.	The Endo GIA™ universal staplers have applications in abdominal, gynecology, pediatric, and thoracic, surgery for resection transection and creation of anastomosis.	The Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and its reload are intended for transection and resection of tissue and vasculature. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures.
Same intended use	Yes	Yes	Yes
Staple line length	30 mm 45 mm	30 mm 45 mm 60 mm	35 mm
Anvil tip configuration	Curved tip anvil	Round tip anvil	Curved-tip anvil
Shaft length (from proximal attachment)	Short (20 cm) and Long (29 cm)	11.25 cm	32 cm
Shaft diameter	12 mm to 8 mm Variable shaft diameter: constructed with shaft diameter of 12 mm approximate at proximal end and 8 mm approximate from narrowed mid-section of shaft to distal working end at end-effector.	12 mm Uniform shaft diameter: constructed with a shaft diameter of 12 mm approximate at proximal end to distal working end at end-effector	9 mm to 12 mm Variable shaft diameter: constructed with a shaft diameter of 9 mm approximate at narrowed proximal end and mid-section of shaft to 12 mm approximate at distal working end at end-effector
Staple Sizes: open leg height (cartridge color)	2.0mm (Gray) 2.5mm (White)	2.0mm (Gray) 2.5mm (White)	2.5 mm (White)
Rows of Staples	4 (2 rows on either side of cut line)	6 (3 rows on either side of cut line)	4 (2 rows on either side of cut line)
Staples per Reload	4 rows x 8 staples/row = 32 total (30mm) 4 rows x 11 staples/row = 44 total (45mm)	6 rows x 8 staples/row = 48 total (30mm) 6 rows x 11 staples/row = 66 total (45mm)	4 rows x 9 staples/row = 36 total (35mm)
Articulation	Yes (max 45°)	Yes (max 45°)	Yes (max 50°)
Single Patient Use	Yes	Yes	Yes
Disposable	Yes	Yes	Yes
Identification of materials of implant (staple) and tissue cutting component (knife)	Staple- Titanium Knife- Stainless Steel	Staple- Titanium Knife- Stainless Steel	Staple – Titanium Knife – Stainless steel

Via the below listed tests, qualitative and quantitative data were obtained and used to compare the Signia™ Small Diameter Reloads to primary predicate Endo GIA™ Auto Suture™ Universal Articulating Loading Units and reference predicate Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and Endopath Echelon™ Vascular White Reload for Advanced Placement Tip.

The design differences were found to not affect the substantial equivalence through applicable design verification activities and risk analysis 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. Functional performance test – Bench and Animal (Acute)
    a. Bench tests
        i. Visual inspection
        ii. Force to load, rotate, and lock reload
        iii. Stapler handle compatibility
        iv. Knife cut
        v. Staple formation in test media
        vi. Firing and retraction forces
        vii. Communications test with Signia™ Powered Handle
        viii. Trocar Insertion/Removal forces
        ix. Pneumo-seal leak rate
        x. Worst Case Ex vivo Burst Pressure including Veins
    b. Animal acute tests
        i. Tissue trauma
        ii. Grasping trauma
        iii. Hemostasis
        iv. Staple formation in intended tissue
2. Chronic survival testing in animal
    a. Chronic study of Signia™ Small Diameter Reload vs. Control (primary and reference predicates) staplers for Lobectomy in the Thorax of a Canine
    b. Chronic study of Signia™ Small Diameter Reload vs. Control (primary and reference predicates) staplers for Nephrectomy, Splenectomy, and Ovariohysterectomy in the Abdomen of a Porcine.
3. Usability Tests per IEC 62366
4. Biocompatibility tests per ISO 10993-1
5. Electrical Safety tests per IEC 60601-1
6. EMC/EMI tests per IEC 60601-1-2
7. Sterilization assessment per ISO 11135
8. Stability/Shelf-life studies

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