November 29, 2022

Covidien
Robert Zott
Senior Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K222641
Trade/Device Name: Signia™ Small Diameter Reloads Including Regular (Round) Tip Version
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: August 30, 2022
Received: September 1, 2022

Dear Robert Zott:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2022.11.29 12:57:00 -05'00'

Mark Trumbore
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team
DHT4A: Division of General 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222641

Device Name

Signia™ Small Diameter Reloads Including Regular (Round) Tip Version

Indications for Use *(Describe)*

The Signia™ small diameter curved tip 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 Signia™ small diameter regular (round) tip white reload has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of thin tissue and vasculature and the creation of anastomosis.

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
K222641

Date Prepared:
August 30, 2022

Submitter:
Covidien
60 Middletown Avenue
North Haven, CT 06473 USA

Contact Person:
Robert Zott
Senior Regulatory Affairs Specialist
Email: robert.zott@medtronic.com
Phone: (917) 421-6878

Identification of Device:

Trade/Proprietary Name:	Signia™ Small Diameter Reloads
Common Name:	Surgical Stapler with Implantable Staples
Regulation Number:	21 CFR 878.4750 / 21 CFR 878.4740
Regulation Name:	Implantable Staple
Device Class:	Class II
Product Code:	GDW / GAG
Review Panel:	General and Plastic Surgery

Predicate Device:

Trade/Proprietary Name:	Signia™ Small Diameter Reloads
Common Name:	Surgical Stapler with Implantable Staples
Regulation Number:	21 CFR 878.4750
Regulation Name:	Implantable Staple
Device Class:	Class II
Product Code	GDW
Review Panel:	General and Plastic Surgery
510(k) Number:	K191070
Manufacturer:	Covidien

Reference Device:

Trade/Proprietary Name:	Endo GIA™ Staplers
Common Name:	Surgical Stapler with Implantable Staples
Regulation Number:	21 CFR 878.4750
Regulation Name:	Implantable Staple
Device Class:	Class II

Product Code:	GDW
Review Panel:	General and Plastic Surgery
510(k) Number:	K111825
Manufacturer:	Covidien

Device Description:

Signia™ Small Diameter Reloads are 8 mm diameter reloads that shall be utilized for open and minimally invasive surgical procedures for the transection and resection of tissue, specifically vascular and thin tissue structures. They shall be offered with both a curved tip (cleared in predicate submission K191070) and a new regular (round) tip model. The Signia™ small diameter regular (round) tip white reloads shall be indicated for use in the creation of anastomosis.

The reload is the distal shaft and jaws of the stapler system comprised of a single-use knife, fixed anvil, and the fixed stapler cartridge with two (2) rows of titanium staples on either side of the cut line**.** The reload is single use only and the cartridges cannot be replaced.

Signia™ Small Diameter Reloads feature a narrow shaft, narrow end-effector, narrow anvil with either a curved tip or regular (round) tip, and multiple articulation angles up to 45 degrees. These features facilitate device access to smaller or tighter surgical spaces (e.g. intercostal) as well as difficult-to-reach vasculature. Signia™ Small Diameter Reloads shall be 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 tip (gray and white) and Regular (Round) tip (white)
- Reload Shaft Length: Short (15 cm) and Long (24 cm)
- Reload Diameter (upper-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. The working length of the Signia™ small diameter reload will fit down an 8mm trocar sleeve or larger, and is compatible with existing Covidien manual and powered stapling handles (see *Section 11.10: Compatible Stapling Handles*). The short shaft length (15 cm) is recommended for use in open, thoracoscopic or laparoscopic procedures and are compatible with appropriately-sized trocar sleeves, 8 mm or larger. The long shaft length (24 cm) is recommended for use in laparoscopic procedures with appropriately-sized trocar sleeves, 8 mm or larger. The Signia™ Small Diameter Reloads are recommended for use with Covidien compatible short stapler adapters and handles. The reloads contain an intelligence chip, which has the ability to communicate with the Covidien powered Signia™ Stapler handle that has a compatible communications interface.

Through this submission, a new reload model SIGSDL45VT with a regular (round) tip anvil shall be added to the stapling family of Signia™ Small Diameter Reloads as a line extension. Additionally, the indications of Signia™ Small Diameter regular (round) tip white reloads shall be expanded to include creation of anastomosis based on the supporting data provided in this submission.

Indications for Use:

The Signia™ small diameter curved tip 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 Signia™ small diameter regular (round) tip white reload has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of thin tissue and vasculature and the creation of anastomosis.

Technological and Performance Characteristics:

The subject curved tip Signia™ Small Diameter Reloads with the revised stapling guidance labeling and the subject regular (round) tip Signia™ Small Diameter Reload with the anastomosis indication and the revised stapling guidance labeling are substantially equivalent to the predicate devices described in K191070 with regard to the stapling technologies employed and the performance characteristics described in the predicate submission. The fundamental operation of the Signia™ Small Diameter Reloads has not changed: to deliver two-staggered rows of titanium staples to either side of the cut line utilizing a narrow shaft, narrow end-effector, narrow anvil with either a curved tip or regular (round) tip, and multiple articulation angles up to 45 degrees. The curved tip and regular (round) tip designs differ only in the shape of the distal tip of the anvil; the pockets of the anvil that form the staples are identical.

Substantial Equivalence Overview Table

Features	**Subject Devices (K222641)** Signia™ Small Diameter Reload Including Regular (Round) Tip	**Predicate Device (K191070)** Signia™ Small Diameter Reload
Indications for use	The Signia™ small diameter curved tip 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 Signia™ small diameter regular (round) tip white reload has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of thin tissue and vasculature and the creation of anastomosis.	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.
Models / Tip Configuration	SIGSDS30CTV - Curved Tip SIGSDS30CTVT - Curved Tip SIGSDL45CTVT - Curved Tip SIGSDL45VT - Regular (Round) Tip	SIGSDS30CTV - Curved Tip SIGSDS30CTVT - Curved Tip SIGSDL45CTVT - Curved Tip Note: All reorder codes in the predicate submission have curved anvil tip design as designated by “CT” in the model name.

Features	Subject Device (K222641) Signia™ Small Diameter Reload Including Regular (Round) Tip	Predicate Device (K191070) Signia™ Small Diameter Reload
Basic Functions: Rotation, Articulation, Clamping, Unclamping, Firing, Retraction, Grasping.	Yes	Yes
Staple Line Length	SIGSDS30CTV (30 mm) SIGSDS30CTVT (30 mm) SIGSDL45CTVT (45 mm) SIGSDL45VT (45 mm)	SIGSDS30CTV (30 mm) SIGSDS30CTVT (30 mm) SIGSDL45CTVT (45 mm)
Shaft Length	SIGSDS30CTV (15 cm) SIGSDS30CTVT (15 cm) SIGSDL45CTVT (24 cm) SIGSDL45VT (24 cm)	SIGSDS30CTV (15 cm) SIGSDS30CTVT (15 cm) SIGSDL45CTVT (24 cm)
Shaft Diameter	Same as Predicate	12 mm (proximal end) to 8 mm (distal end)
Staple Sizes: (Open Leg Height / Cartridge Color)	SIGSDS30CTV (2.0 mm / Gray) SIGSDS30CTVT (2.5 mm / White) SIGSDL45CTVT (2.5 mm / White) SIGSDL45VT (2.5 mm / White)	SIGSDS30CTV (2.0 mm / Gray) SIGSDS30CTVT (2.5 mm / White) SIGSDL45CTVT (2.5 mm / White)
Target Thickness Range	Same as Predicate	1.0 – 1.5 mm (White) 0.75 – 1.00mm (Gray)
Rows of Staples	Same as Predicate	4 Total (2 rows on either side of cut line)
Staples per Reload	Same as Predicate	32 total (30 mm cartridge) 44 total (45 mm cartridge)
Articulation	Same as Predicate	Yes (max 45°)
Single Patient Use & Disposable	Same as Predicate	Yes
Materials of Staple and Knife	Same as Predicate	Staple: Titanium Knife: Stainless Steel

Features	Subject Device (K222641) Signia™ Small Diameter Reload Including Regular (Round) Tip	Predicate Device (K191070) Signia™ Small Diameter Reload
Device Compatibility	Same as Predicate	Compatible with Covidien manual and powered stapler handles.
1-Wire® communication capability with Signia™ Power Handle	Same as Predicate	Yes
Biocompatibility	Same as Predicate	Materials used were evaluated in accordance with ISO 10993-1 Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing.

Summary of Studies:

Performance testing completed for the Signia™ small diameter curved tip reloads was submitted, reviewed and cleared in the predicate submission (K191070). This testing demonstrated both substantial equivalence to legally marketed devices as well as establishing performance specifications for its intended use and indications for use. Additional testing for the regular (round) tip reload included the chronic testing and usability for anastomosis, supported by clinical literature.

Differing only in the anvil's distal tip geometry, all remaining technological characteristics including aspects of design, dimensional specifications, and manufacturing between the new regular (round) tip reload model SIGSDL45VT and the predicate curved tip model SIGSDL45CTVT remain the same, including but not limited to the implantable staple design, anvil pocket design, knife design, and cartridge design. The previously-submitted performance data for the predicate curved tip model SIGSDL45CTVT remains applicable to the new regular (round) tip model. The difference in the anvil tip shape does not impact stapling performance and does not raise different questions of safety and effectiveness when compared with the predicate device. The following is the summary of all the appliable performance testing.

Tests performed to evaluate and compare technological and performance characteristics:

1. 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 Reloads vs. Control (predicate and reference device) for Lobectomy in the Thorax of a Canine;

b. Chronic study of Signia™ Small Diameter Reloads vs. Control (predicate and reference device) for Nephrectomy, Splenectomy, and Ovariohysterectomy in the Abdomen of a Porcine**.**

c. Chronic study of Signia™ Small Diameter Regular (Round) Tip Reload vs. Control (reference device) for Jeju-Jejunostomy in the Small Bowel of a Canine model.

3. Human Factors / Usability Tests per IEC 62366-1 and Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff Document, issued on February 3, 2016, for general use, labeling, and anastomosis.

4. Biocompatibility tests per ISO 10993-1 and Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff Document, issued on September 4, 2020.

5. Electrical Safety tests per IEC 60601-1.

6. Electromagnetic Compatibility (EMC) per IEC 60601-1-2.

7. Sterilization assessment per ISO 11135.

8. Stability / Shelf-life studies.

9. Published clinical literature.

In addition, labeling was updated in accordance with Surgical Staplers and Staples for Internal Use - Labeling Recommendations, Guidance for Industry and Food and Drug Administration Staff Document, issued on October 8, 2021.

No clinical study was performed and no clinical data is provided, herein. Substantial equivalence has been demonstrated by non-clinical and preclinical studies.

Reference Device:

In addition to the predicate device, Endo GIA™ staplers (K111825) was cited in this submission for additional comparison as it was previously cleared for the creation of anastomosis. Endo GIA™ staplers were used in comparative performance testing as a control device in both the predicate submission K191070 and the chronic study for anastomosis.

Conclusion:

Based upon the data summarized above, Covidien concludes that the subject Signia™ Small Diameter Reloads including both the curved tip and regular (round) tip are as safe and effective as the predicate devices legally marketed under K191070, and do not raise different questions of safety and effectiveness when compared with the predicate device.