November 01, 2024

Covidien (Part of Medtronic)
Carolina Cabezas
Sr. Regulatory Affairs Specialist
60 Middletown Ave.
North Haven, Connecticut 06473

Re: K240881
Trade/Device Name: Signia™ Circular Adapter (Standard Length) (SIGCIRSTND); Signia™ Circular Adapter XL Length (SIGCIRXL) (For use with Signia™ Stapler)
Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical stapler
Regulatory Class: Class II
Product Code: GAG, GDW
Dated: March 29, 2024
Received: April 1, 2024

Dear Carolina Cabezas:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.11.01 11:29:48 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K240881

Device Name
Signia™ Circular Adapter (Standard Length) (SIGCIRSTND);
Signia™ Circular Adapter XL Length (SIGCIRXL)

Indications for Use *(Describe)*
The Signia™ stapler, when used with the Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads, has applications throughout the alimentary tract for the creation of end-to-end, end-to-side, and side-to-side anastomoses in both open and laparoscopic surgeries.

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:

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*"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."*

K240881

# 510(k) Summary

**DATE PREPARED:**
November 1, 2024

**SUBMITTER:**
Covidien
60 Middletown Avenue
North Haven, CT 06473 USA

**CONTACT PERSON:**
Carolina Cabezas
Sr. Regulatory Affairs Specialist
Telephone: (203) 492-6054
carolina.m.cabezas@medtronic.com

**IDENTIFICATION OF DEVICE:**

| | |
|---|---|
| Proprietary/Trade Name: | Signia™ Circular Adapter (Standard Length) (SIGCIRSTND); Signia™ Circular Adapter XL Length (SIGCIRXL) |
| Classification Name: | Surgical Stapler |
| Regulation Number: | 21 CFR 878.4740 |
| Device Class: | Class II |
| Product Code: | GAG (Primary), GDW (Secondary) |
| Review Panel: | General and Plastic Surgery |
| Common Name: | Surgical Stapler |

**PREDICATE DEVICE:**

| | |
|---|---|
| 510(k) Number | K221629 (Feb 22, 2023) |
| Proprietary/Trade Name | Tri-Staple 2.0 Black Circular Reloads (for use with Signia Circular Adapters) |
| Classification Name | Surgical Stapler |
| Regulation Number | 21 CFR 878.4740 |
| Device Class | Class II |
| Product Code | GAG, GDW |
| Review Panel | General and Plastic Surgery |
| Common Name | Surgical Stapler |

**DEVICE DESCRIPTION:**

The Signia™ circular adapters are reusable instruments that connect with the assembled Signia™ power handle and Signia™ power shell to make up the Signia™ stapler. The Signia™ circular adapters are composed of motor-mating connectors, sensor gauges and device communication interfaces to provide functionality and communication between compatible reloads and the Signia™ stapler. The Signia™ circular adapters are available in two shaft lengths, standard (25 cm) and extra-long (30 cm).

The Signia™ Circular Adapter are for use with the Signia™ Stapler. The Signia™ stapler, when used with the Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads, is a battery powered microprocessor controlled surgical stapler that provides push-button powered operations and firing of compatible reloads. The Signia™ stapler is intended to be used by medical professionals qualified in the transportation, preparation, cleaning, sterilization, and use of surgical devices. The Signia™ stapler is intended for use in a sterile operating room environment in surgical procedures where surgical stapling is

indicated. Signia™ Stapler can be used for both linear and circular stapling application depending on the software version installed in the Signia™ power handle.

**INDICATIONS FOR USE:**
The Signia™ stapler, when used with the Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads, has applications throughout the alimentary tract for the creation of end-to-end, end-to-side, and side-to-side anastomoses in both open and laparoscopic surgeries.

**TECHNOLOGICAL CHARACTERISTICS:**

The modified Signia™ circular adapters have the same intended use, material, and operational principles as the predicate Signia™ circular adapters (K221629). The design of the modified Signia™ circular adapters remains similar to the predicate Signia™ circular adapters (K221629). The main difference between the subject Signia™ circular adapters and the predicate Signia™ circular adapters is that the subject adapters have a fixed trocar rather than a removable trocar design. The function and use of the circular adapters remain the same as the predicate K221629.

**NON-CLINICAL TESTING:**

The below non-clinical testing was performed:

- Reprocessing per ISO 17664
- Sterilization per ISO 11135
- Stability/Shelf Life
- Biocompatibility per ISO 10993-1
- Software verification & validation activities completed per IEC 62304
- Cybersecurity Assessment following FDA's Guidance *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*" issued September 27, 2023.
- Electrical safety report per ANSI/AAMI ES 60601-1 & IEC 60601-1 and electromagnetic compatibility (EMC) report per IEC 60601-1-2
- Performance testing such as bench top, *in-vivo* and *ex-vivo* animal testing
- Chronic animal study
- Usability evaluation performed per IEC 62366-1
- Reliability testing

Previously demonstrated compliance for the following aspects remains unimpacted:

- MR safety information has been previously cleared via K221629 and no change has been made to impact MR characteristics.
- Ethylene oxide (EO) sterilization validation for the single use devices with a minimum Sterility Assurance Level (SAL) of $10^{-6}$

**CLINICAL TESTING:**
This submission does not require clinical testing.

**CONCLUSION:**
Based upon the supporting data summarized above, the modified Signia™ circular adapters, when used with the existing Signia™ stapler, are substantially equivalent to the legally marketed predicate devices.