March 3, 2023

Covidien
Katherine Choi
Sr. Principal Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K221629
Trade/Device Name: Tri-Staple™ 2.0 Black Circular Reloads (for use with Signia™ Circular Adapters)
Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical stapler
Regulatory Class: Class II
Product Code: GAG, GDW

Dear Katherine Choi:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 02/22/2023. Specifically, FDA is updating this SE Letter, **the Primary Product Code and the Secondary Product Code were reversed,** as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact **Mark Trumbore**, **Office of Product Evaluation and Quality**, **301-796-5436, Mark.Trumbore@FDA.HHS.Gov**.

Sincerely,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.03.03 09:01:33 -05'00'

Mark Trumbore
Assistant Director
THT4A1: Robotically-Assisted Surgical Device Team
DHT4A: Devision of General Surgery Devices
OHT4: Division of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

February 22, 2023

Covidien
Katherine Choi
Sr. Principal Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K221629
Trade/Device Name: Tri-Staple™ 2.0 Black Circular Reloads (for use with Signia™ Circular Adapters)
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: January 23, 2023
Received: January 23, 2023

Dear Katherine Choi:

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: 2023.02.22 15:15:45 -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)*

Device Name
Tri-Staple™ 2.0 Black Circular Reloads (for use with Signia™ Circular Adapters)

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.

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Appendix H

Updated 510(k) Summary

510(k) Summary

DATE PREPARED:
January 23, 2023

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

CONTACT PERSON:
Katherine Y. Choi, RAC
Sr. Principal Regulatory Affairs Specialist
Telephone: (203) 492-8412

IDENTIFICATION OF DEVICE:

Proprietary/Trade Name:	Tri-Staple 2.0 Black Circular Reloads (for use with Signia Circular Adapters)
Classification Name:	Staples, Implantable
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 DEVICES:

	Primary Predicate	Secondary Predicate
510(k) Number	K182475 (Mar 14, 2019)	K192330 (Jan 23, 2020)
Proprietary/Trade Name	Signia Circular Adapters (for use with Signia Staplers), Tri-Staple 2.0 Circular Reloads (for use with Signia Circular Adapters)	EEA™ circular stapler with Tri-Staple™ technology
Classification Name	Staple, Implantable	Staple, Implantable
Regulation Number	21 CFR 878.4750	21 CFR 878.4750
Device Class	Class II	Class II
Product Code	GDW, GAG	GDW
Review Panel	General and Plastic Surgery	General and Plastic Surgery
Common Name	Surgical Stapler	Surgical Stapler

DEVICE DESCRIPTION:
The Tri-Staple™ 2.0 black circular reloads place a circular triple staggered row of titanium staples. After staple formation, the knife blade resects the excess tissue, creating a circular anastomosis such as end-to-end, end-to-side, or side-to-side anastomosis as the user sees fit. The new circular reloads will be offered for an extra thick tissue thickness range, which is identified by the black staple guide. The circular reloads deploy three height-progressive rows of 4.0 mm, 4.5 mm and 5.0 mm staples. The Tri-Staple™ technology incorporated in the black reload is essentially the same as the legally-marketed K192330 in terms of reload design. The Tri-Staple™ 2.0 black circular reloads are provided sterile for single use, and available in three lumen sizes: 28, 31, and 33 mm. The Tilt-Top™ anvil is available with all circular reloads.

The Tri-Staple™ 2.0 black reloads are for use with the previously-marketed Signia™ Circular Adapter, as part of 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.

As part of this submission, additional design improvements implemented since K182475 are described.

This submission also addresses the new requirements applicable to the powered circular stapler under FDA's Final Order 2021-22041 and the new FDA's guidance titled "Surgical Staplers and Staples for Internal use – Labeling Recommendations." (issued on October 8, 2021).

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.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:
All Tri-Staple™ 2.0 circular reloads are, as implied by the product name, designed with Covidien's proprietary Tri-Staple™ technology. The technology incorporates the triple staggered rows of titanium staples with different staple height in each staple row. It has a stepped configuration whereby the staples in the outer most row are the tallest and the staples in the inner most row are the smallest. The staple cartridge has a sloping tissue surface which provides for a graduated tissue gap, and provides for each row of staples to effectively have its own tissue gap.

The Tri-Staple™ 2.0 black reloads are for use with Signia™ stapler, which employs the powered stapling technology. The advantages of powered stapling, such as push-button operations, software-controlled tissue compression, stapling, and cutting are included, which resulted in consistent staple lines when compared to the manual instrument where the same actions are achieved through the user's manual force. After staple formation, the knife blade resects the excess tissue, creating a circular anastomosis.

Above fundamental technologies stay the same as K182475 except for the following design difference:
The new reloads will be offered for an extra thick tissue range, which is identified by the black staple guide. The reloads deploy three (3) height-progressive rows of 4.0 mm, 4.5 mm and 5.0 mm titanium staples. The Tri-Staple™ technology incorporated in the new 'black' reloads is identical to the marketed manual circular staplers cleared under K192330.

SUBSTANTIAL EQUIVALENCE:
The below table summarizes the similarities and differences between the subject and predicate devices.

Feature	Subject Device	Primary Predicate K182475	Secondary Predicate K192330
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.	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.	The EEA™ Circular Stapler with Tri-Staple™ Technology has application 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.
Target Anatomy	Alimentary tract	Alimentary tract	Alimentary tract
Surgical procedures	Both open and laparoscopic surgeries	Both open and laparoscopic surgeries	Both open and laparoscopic surgeries
Operating Principle	Software-controlled and powered by a built-in battery with push button controls. The CTC is now called Adaptive Compression Technology (ACT).	Software-controlled and powered by a built-in battery with push button controls, and Controlled Tissue Compression (CTC) feature	Manual - activated by squeezing the handle firmly as far as it will go.
Stapler Shaft Length	Circular Adapter - Standard: 25cm Circular Adapter - XL: 30cm	Circular Adapter - Standard: 25cm Circular Adapter - XL: 30cm	Standard length: 22cm Extra length XL: 35cm
Audible Feedback	Electronic beeps	Electronic beeps	Manual clicks
Firing Force	Pushing the toggle key to fire	Pushing the toggle key to fire	Manual squeezing to fire
Safety Features	Error handlings and Recovery modes	Error handlings and Recovery modes	Safety Lever (red color)
Intelligent interface	Yes - provides intelligent interface of reloads and adapters with ID-chips	Yes - provides intelligent interface of reloads and adapters with ID-chips	No – manual instrument without any ID chips or electronic parts
Biocompatibility	Evaluated per ISO 10993 series and FDA 2016 biocompatibility guidance	Evaluated per ISO 10993 series and FDA 2016 biocompatibility guidance	Evaluated per ISO 10993 series and FDA 2016 biocompatibility guidance
Circular Reloads			
Staple Design	Tri- Staple™ Technology	Tri- Staple™ Technology	Tri-Staple™ Technology
Staple Rows	3 staggered rows of staples with different staple height in each staple row	3 staggered rows of staples with different staple height in each staple row	3 staggered rows of staples with different staple height in each staple row
Staple Material	Titanium per ASTM F67 Grade I	Titanium per ASTM F67 Grade I	Titanium per ASTM F67 Grade I
Guide Color	Black	Purple	Black
Staple Height	4.0mm, 4.5mm 5.0mm	3.0mm, 3.5mm, 4.0mm	4.0mm, 4.5mm 5.0mm
Closed Heights	1.5mm, 1.75mm, 2.0mm	1.2mm, 1.5mm, 1.75mm	1.5mm, 1.75mm, 2.0mm
Indicated Tissue Thickness Range	Extra Thick (black) reloads: 2.25 - 3.0mm (0.090” – 0.120”)	Medium/Thick (purple) reloads: 1.5 - 2.25mm (0.060” - 0.090”)	Extra Thick (black) reloads: 2.25 - 3.0mm (0.090” – 0.120”)
Shell Diameter/ Lumen Sizes	28mm/31mm/33mm	21mm/25mm/28mm/31mm/33mm	28mm/31mm/33mm 25mm added later by K202507
Sterilization	Ethylene oxide (EO)	Ethylene oxide (EO)	Ethylene oxide (EO)
Biocompatibility-Reloads	Evaluated per ISO 10993 series and FDA 2016 biocompatibility guidance	Evaluated per ISO 10993 series and FDA 2016 biocompatibility guidance	Evaluated per ISO 10993 series and FDA 2016 biocompatibility guidance

SUMMARY OF STUDIES:

Non-clinical performance data – The following studies have been performed to demonstrate substantial equivalence to the predicate devices. When possible, applicable FDA-recognized standards were considered:

- Stability/Shelf-Life study for the single use devices
- Performance testing such as bench top, *ex-vivo, and in-vivo* pre-clinical testing
- Usability study performed following the FDA's 2016 guidance as well as IEC 62366-1
- Chronic GLP study performed to evaluate the performance in healing metrics and anastomotic index

To address additional design improvements implemented to the previously cleared device, the following supporting data has been included:

- Disinfection validation performed per the FDA 2015 reprocessing guidance
- Reliability data supporting the extended end of life of the reusable devices
- Biocompatibility evaluation conducted in accordance with the FDA's 2020 guidance and ISO 10993-1
- Software verification & validation activities completed following the FDA's guidance documents and IEC 62304
- Cleaning reprocessing validated following the FDA 2015 reprocessing guidance
- Electrical safety testing repeated per ANSI/AAMI ES 60601-1 & IEC 60601-1 and electromagnetic compatibility (EMC) testing per IEC 60601-1-2

MR safety information has been previously cleared via K182475 and no change has been made to impact MR characteristics, but testing has been repeated per the latest applicable standards.

Previously demonstrated compliance for the following aspects remains unimpacted:

- Sterilization reprocessing validated following the FDA 2015 reprocessing guidance
- Ethylene oxide (EO) sterilization validation for the single use devices with a minimum Sterility Assurance Level (SAL) of 10^{-6}

Clinical performance data – No clinical study is deemed necessary since the substantial equivalence has been sufficiently demonstrated through non-clinical studies.

CONCLUSION:

Based upon the supporting data summarized above, we concluded that the new Tri-Staple™ 2.0 black circular reloads, when used with the already-marketed Signia™ stapler, are as safe and effective as the legally marketed predicate devices, and do not raise different questions of safety and effectiveness than the predicate devices.