July 01, 2026

Covidien, LLC
Frank Maistrovich
Principal Regulatory Affairs Specialist
60 Middletown Ave.
North Haven, Connecticut 06473

Re: K253527
Trade/Device Name: Tri-Staple™ 2.0 Black Circular Reload 21mm Extra Thick (SIGCIR21XT); Tri-Staple™ 2.0 Black Circular Reload 25mm Extra Thick (SIGCIR25XT)
Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical Stapler
Regulatory Class: Class II
Product Code: GAG, GDW
Dated: June 1, 2026
Received: June 1, 2026

Dear Frank Maistrovich:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253527

Please provide the device trade name(s).

Tri-Staple™ 2.0 Black Circular Reload 21mm Extra Thick (SIGCIR21XT);
Tri-Staple™ 2.0 Black Circular Reload 25mm Extra Thick (SIGCIR25XT)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

510(k): K253527

Date Prepared: 01-Jul-2026

Contact Details

Applicant Name	**COVIDIEN LLC**
Applicant Address	**60 Middletown Ave. North Haven CT 06473 United States**
Applicant Contact Telephone	**952.738.2339**
Applicant Contact	**Mr. Frank Maistrovich**
Applicant Contact Email	**Frank.D.Maistrovich@medtronic.com**

Device Name

Device Trade Name	**Tri-Staple™ 2.0 Black Circular Reload 21mm Extra Thick (SIGCIR21XT);** **Tri-Staple™ 2.0 Black Circular Reload 25mm Extra Thick (SIGCIR25XT)**
Common Name	**Surgical stapler**
Classification Name	**Stapler, Surgical**
Regulation Number	**878.4740**
Product Code(s)	**GAG, GDW**

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221629	**Tri-Staple™ 2.0 Black Circular Reloads (for use with Signia™ Circular Adapters)**	**GAG**
K202507	**EEA Circular Stapler with Tri-Staple Technology**	**GDW**
K221771	**EEA Circular Stapler with Tri-Staple Technology**	**GDW**

Device Description Summary

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 black circular reloads deploy three height progressive rows of 4.0mm, 4.5mm, and 5.0mm staples. The subject Tri-Staple™ 2.0 black circular reload introduces new lumen sizes of 21 and 25mm.

The Tri-Staple™ 2.0 black circular reloads are provided sterile for single use.

The Tri-Staple™ 2.0 black circular reloads and the Signia™ circular adapters 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 applications.

Intended Use / 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.

Indications for Use Comparison

The subject device indications for use are identical the predicate indications for use.

Technological Comparison

The Tri-Staple™ 2.0 black circular reloads are offered in new lumen sizes 21mm and 25mm have the same intended use, material, design (except size), and operational principles as the predicate Tri-Staple™ 2.0 black circular reloads. The subject devices also have the same intended use and lumen size range as the secondary predicates, manual EEA™ Circular Stapler with Tri-Staple™ Technology (K202507 / K221771).

Non-Clinical and/or Clinical Tests Summary & Conclusions

Performance / Non-Clinical Testing

The following non-clinical testing was performed:

- Sterilization per ISO 11135;
- Stability/Shelf Life;
- Biocompatibility per ISO 10993-1;
- Electrical safety per ANSI/AAMI ES 60601-1 & IEC 60601-1 and electromagnetic compatibility (EMC) per IEC 60601-1-2;
- Performance testing including bench top, in-vivo and ex-vivo animal testing;
- Chronic animal testing;

• Usability evaluation per IEC 62366-1.

Other testing areas/categories are unaffected, and the predicate testing continues to be valid.

Clinical Testing

No clinical testing was required.

Predetermined Change Control Plan (PCCP)

Planned Modification

The predetermined change control plan (PCCP) for the device specifies an anticipated modification to the TILT-TOP anvil used with TRI-STAPLE 2.0 circular reload family of devices. PVC tubing will be attached to the anvil to create a transoral, “ORVIL” anvil.

Test Method and Validation Activities

The PCCP also specifies the methods to implement the ORVIL modification so that the device remains as safe and as effective as the predicate device. The testing will be completed in accordance with the authorized PCCP and will include the following:

• Sterilization per ISO 11135;

• Stability/Shelf Life;

• Performance testing including bench top.

Communication to Users, as needed

In order to communicate implementation of the modification to users, TRI-STAPLE 2.0 circular reloads including ORVIL will be sold under / labeled with new, unique device numbers. TRI-STAPLE 2.0 circular reloads including ORVIL will also be packaged with an Instructions for Use document specific for devices including ORVIL.

Conclusion

Based upon the supporting data summarized above, the Tri-Staple™ 2.0 black circular reloads 21mm and 25mm, when used with the existing Signia™ stapler, demonstrates substantial equivalence to the legally marketed predicate devices.