April 10, 2026

Covidien (Part of Medtronic)
Fei Li
Principal Regulatory Affairs Specialist
60 Middletown Ave.
North Haven, Connecticut 06473

Re: K253657
Trade/Device Name: Tri-staple 2.0™ Reloads; Endo GIA™ Reloads with Tri-Staple™ Technology; Endo GIA™ Gray Articulating Reloads; Signia™ Small Diameter Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Codes: GDW, GAG
Dated: March 10, 2026
Received: March 10, 2026

Dear Fei Li:

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 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.	K253657

Please provide the device trade name(s).

Tri-staple 2.0™ Reloads;
Endo GIA™ Reloads with Tri-Staple™ Technology;
Endo GIA™ Gray Articulating Reloads;
Signia™ Small Diameter Reloads

Please provide your Indications for Use below.

The Tri-Staple™ 2.0 reloads are indicated for use in abdominal, urologic, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures, and for transection and resection of pancreas.
The Tri-Staple™ 2.0 curved tip reloads can be used to blunt dissect or separate target tissue from other tissue.

The Endo GIA™ Ultra universal short, Endo GIA™ Ultra universal and Endo GIA™ Ultra universal XL staplers and Endo GIA™ reloads with Tri-Staple™ technology are indicated for use in abdominal, urologic, gynecologic, pediatric, and thoracic surgery for resection, transection and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures, and for transection and resection of pancreas.
The Endo GIA™ Ultra universal short, Endo GIA™ Ultra universal and Endo GIA™ Ultra universal XL staplers when used with the Endo GIA™ curved tip single use reloads can be used to blunt dissect or separate target tissue from other tissue.

The Signia™ small diameter reloads are indicated for use in abdominal, urologic, gynecologic, pediatric and thoracic surgery for resection and transection of vasculature using gray reloads and thin tissue and vasculature using white reloads.

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)

K253657

510(k) Summary

DATE PREPARED:
April 10, 2026

SUBMITTER:
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IDENTIFICATION OF DEVICE:

Proprietary/Trade Name:	Tri-staple 2.0™ Reloads Endo GIA™ Reloads with Tri-Staple™ Technology Endo GIA™ Gray Articulating Reloads Signia™ Small Diameter Reloads
Classification Name:	Staples, Implantable
Regulation Number:	21 CFR 878.4750, 21 CFR 878.4740
Device Class:	Class II
Product Code:	GDW, GAG
Review Panel:	General and Plastic Surgery
Common Name:	Implantable staple

PREDICATE DEVICES:

	Primary Predicate 1	Primary Predicate 2	Primary Predicate 3	Secondary Predicate 1	Secondary Predicate 2
510(k) Number	K202864	K111825	K222641	K241629	K141952
Proprietary/Trade Name	Tri-Staple™ 2.0 Reloads	Endo GIA™ Staplers, DST Series™ GIA Staplers, DST Series™ TA Staplers	Signia™ Small Diameter Reloads	ECHELON™ 3000 45mm Standard Stapler (ECH45S) ECHELON™ 3000 45mm Long Stapler (ECH45L) ECHELON™ 3000 60mm Compact	Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip, and Endopath Echelon™ Vascular White Reloads for Advanced

				Stapler (ECH60C) ECHELON™ 3000 60mm Standard Stapler (ECH60S) ECHELON™ 3000 60mm Long Stapler (ECH60L)	Placement Tip
Classification Name	Staples, Implantable	Staple, Implantable	Staple, Implantable	Stapler, Surgical	Staple, Implantable
Regulation Number	21 CFR 878.4750	21 CFR 878.4750	21 CFR 878.4750 / 21 CFR 878.4740	21 CFR 878.4740	21 CFR 878.4750
Device Class	Class II	Class II	Class II	Class II	Class II
Product Code	GDW	GDW	GDW, GAG	GAG	GDW
Review Panel	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
Common Name	Implantable staples	Implantable staples	Implantable Staples	Surgical Stapler	Surgical Stapler with Implantable Staples

DEVICE DESCRIPTION:

Tri-Staple™ 2.0 Reloads
The Tri-Staple™ 2.0 reloads and Tri-Staple™ 2.0 curved tip reloads place staggered rows of titanium staples and simultaneously divides the tissue so that three 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 Tri-Staple™ 2.0 reload is available in articulating 30 mm, 45 mm and 60 mm length, the Tri-Staple™ 2.0 curved tip reload is available in articulating 30 mm, 45 mm and 60 mm lengths and the Tri-Staple™ 2.0 black reload is available in articulating 45 mm and 60 mm lengths.

Tri-Staple™ 2.0 Extra Thin/Vascular Reloads:
Gray 30 mm reload, gray 30 mm curved tip reload, gray 45 mm reload and gray 45 mm curved tip reload – three rows of 2.0 mm titanium staples on either side of the cut line.

Tri-Staple™ 2.0 Vascular/ Medium Reloads:
Tan 30 mm reload, tan 30 mm curved tip reload, tan 45 mm reload, tan 45 mm curved tip reload, tan 60 mm reload and tan 60 mm curved tip reload - three height progressive rows of 2.0 mm, 2.5 mm, 3.0 mm titanium staples on either side of the cut line.

Tri-Staple™ 2.0 Medium/ Thick Reloads:
Purple 30 mm reload, purple 45 mm reload, purple 45 mm curved tip reload, purple 60 mm reload and purple 60 mm curved tip reload - three height progressive rows of 3.0 mm, 3.5 mm and 4.0 mm titanium staples on either side of the cut line.

Tri-Staple™ 2.0 Extra Thick Reload:

Black 45 mm reload and black 60 mm reload - three height progressive rows of 4.0 mm, 4.5 mm and 5.0 mm titanium staples on either side of the cut line.
The curved tip on the distal-end of the curved tip reload can be used to dissect and manipulate tissue/vessels when locating target tissue for subsequent firing and placement of staples.

The Tri-Staple™ 2.0 reloads and Tri-Staple™ 2.0 curved tip reloads can be used with the Endo GIA™ Universal, Endo GIA™ Ultra, iDrive™, and Signia™ platforms.

Endo GIA™ Reloads with Tri-Staple™ Technology, Endo GIA™ Gray Articulating Reloads
The Endo GIA™ Reloads with Tri-Staple™ Technology and Endo GIA™ Gray Articulating Reloads place staggered rows of titanium staples and simultaneously divide the tissue so that three 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:

Endo GIA™ single use articulating Extra Thin/Vascular reload:
Gray reload and gray curved tip reload - three rows of 2.0 mm titanium staples on either side of the cut line.

Endo GIA™ single use articulating Vascular/Medium reload with Tri-Staple™ technology:
Tan reload and tan curved tip reload - three height progressive rows of 2.0 mm, 2.5 mm, 3.0 mm titanium staples on either side of the cut line.

Endo GIA™ single use articulating Medium/Thick reload with Tri-Staple™ technology:
Purple reload and purple curved tip reload - three height progressive rows of 3.0 mm, 3.5 mm and 4.0 mm titanium staples on either side of the cut line.

Endo GIA™ single use articulating Extra Thick reloads with Tri-Staple™ technology:
Black reload - three height progressive rows of 4.0 mm, 4.5 mm and 5.0 mm titanium staples on either side of the cut line.

The curved tip on the distal-end of the curved tip reload can be used to dissect and manipulate tissue/vessels when locating target tissue for subsequent firing and placement of staples.

Endo GIA™ reloads are compatible with the following Covidien staplers: Endo GIA™ universal, Endo GIA™ Ultra, iDrive™, and Signia™ platforms.

Signia™ Small Diameter Reloads

The Signia™ small diameter reloads place staggered rows of titanium staples and simultaneously divide 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 reloads place two rows of titanium staples on either side of the cut line and are available in multiple articulating configurations with 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
- Shaft Length: Short (15 cm) and Long (24 cm)
- Shaft Diameter: 8 mm

The curved tip on the distal-end of the curved tip reload can be used to aid in positioning the reload around target tissue/vessels for subsequent firing and placement of staples.

The Signia™ small diameter reloads can be used with the Endo GIA™ Universal, Endo GIA™ Ultra, iDrive™, and Signia™ platforms.

INDICATIONS FOR USE:

Tri-Staple 2.0™ Reloads

The Tri-Staple™ 2.0 reloads are indicated for use in abdominal, urologic, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures, and for transection and resection of pancreas.

The Tri-Staple™ 2.0 curved tip reloads can be used to blunt dissect or separate target tissue from other tissue.

Endo GIA™ Reloads with Tri-Staple™ Technology, Endo GIA™ Gray Articulating Reloads

The Endo GIA™ Ultra universal short, Endo GIA™ Ultra universal and Endo GIA™ Ultra universal XL staplers and Endo GIA™ reloads with Tri-Staple™ technology are indicated for use in abdominal, urologic, gynecologic, pediatric, and thoracic surgery for resection, transection and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures, and for transection and resection of pancreas.

The Endo GIA™ Ultra universal short, Endo GIA™ Ultra universal and Endo GIA™ Ultra universal XL staplers when used with the Endo GIA™ curved tip single use reloads can be used to blunt dissect or separate target tissue from other tissue.

Signia™ Small Diameter Reloads

The Signia™ small diameter reloads are indicated for use in abdominal, urologic, gynecologic, pediatric and thoracic surgery for resection and transection of vasculature using gray reloads and thin tissue and vasculature using white reloads.

TECHNOLOGICAL CHARACTERISTICS:

With the exception of the newly added urologic indication, the subject devices (Tri-Staple™ 2.0 Reloads, Endo GIA™ Reloads with Tri-Staple™ Technology, Endo GIA™ Gray Articulating Reloads, Signia™ Small Diameter Reloads) are identical to the respective primary predicate devices (K202864, K111825, K222641) in regard to intended use, material, design, and operational principles.

SUBSTANTIAL EQUIVALENCE COMPARISON:

The subject devices, primary predicate devices and secondary predicate devices share the same intended use. Regarding the indications for use, the subject devices are IDENTICAL to primary predicates (K202864, K111825, K222641), except for the urology indication. Both the subject devices and the secondary predicates (K241629, K141952) have urology indications.

PERFORMANCE DATA:

Except for the newly added urologic indication, there are no changes to the subject devices regarding the intended use, material, design, and operational principles. Therefore, the subject devices remain substantially equivalent to the predicate devices and no testing is required.

A combination of real-world evidence, post market clinical follow-up, and published clinical literature is provided to support the addition of the urology indication. This data demonstrates the safe and effective use of the subject devices in urologic procedures such as nephrectomy, prostatectomy, and cystectomies, and captures performance metrics across diverse patient populations and surgical settings.

CONCLUSION:

Based upon the supporting data summarized above, the subject devices (Tri-staple 2.0™ Reloads, Endo GIA™ Reloads with Tri-Staple™ Technology, Endo GIA™ Gray Articulating Reloads, Signia™ Small Diameter Reloads) are substantially equivalent to the predicate devices (K202864, K111825, K222641, K241629, K141952).