October 27, 2023

Covidien
Angela Van Arsdale
Sr. Regulatory Affairs Manager
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K231934
Trade/Device Name: GIA™ Stapler with Tri-Staple™ Technology
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: September 27, 2023
Received: September 27, 2023

Dear Angela Van Arsdale:

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.10.27 07:50:21 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
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Office of Product Evaluation and Quality
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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
GIA™ Stapler with Tri-Staple™ Technology

Indications for Use *(Describe)*
The GIA™ stapler with Tri-Staple™ technology has applications in abdominal and thoracic surgical procedures for resection, transection and 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

Date Prepared:
Jun 30, 2023

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Name of Device:

Proprietary/Trade Name:	GIA™ Stapler with Tri-Staple™ Technology
Model Numbers:	GIA80TMS, GIA60TMS, GIA80TMC, GIA60TMC
Classification Name:	Stapler, Surgical; Staple, Implantable
Regulations Number:	21 CFR 878.4740, 21 CFR 878.4750
Product Codes:	GAG, GDW
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical stapler with implantable staples

Predicate Device:

Proprietary/Trade Name:	GIA™ Stapler with Tri-Staple™ Technology
510(k) Number:	K221006
Classification Name:	Stapler, Surgical; Staple, Implantable
Regulations Number:	21 CFR 878.4740, 21 CFR 878.4750
Product Codes:	GAG, GDW
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical stapler with implantable staples

Reference Device:

Proprietary/Trade Name:	GIA™ Stapler with DST Series™ Technology
510(k) Number:	K221013
Classification Name:	Stapler, Surgical; Staple, Implantable

Regulations Number:	21 CFR 878.4740, 21 CFR 878.4750
Product Codes:	GAG, GDW
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical stapler with implantable staples

Device Description:
The GIA™ stapler with Tri-Staple™ technology places two triple staggered rows of titanium staples and simultaneously cuts and divides tissue between these two triple rows. The GIA™ staplers and cartridges with Tri-Staple™ technology are currently available in 60mm and 80 mm length.

The subject device provides the thin/medium staple size. Staplers for thin/medium tissue (tan) deploy three height-progressive rows of 2.4 mm, 2.7 mm and 3.0 mm titanium staples.

Each GIA™ stapler with Tri-Staple™ technology may be reloaded with a GIA™ Cartridge with Tri-Staple™ Technology up to 7 times for a total of 8 firings per instrument.

Both the subject device and the predicate device (K221006) are from the same product family GIA™ Stapler with Tri-Staple™ Technology. The subject device GIA™ Stapler with Tri-Staple™ Technology (staple size 2.4mm, 2.7mm, 3.0mm) provides the surgeons a choice of additional staple size selection to best suit the target anatomy.

The subject device is manufactured with essentially the same patient contact materials that are utilized within the predicate device (K221006).

The GIA™ stapler with Tri-Staple™ technology has the same operation principle as the predicate device. The GIA™ Stapler with Tri-Staple™ Technology is a single-use device. It is packaged and sterilized via ETO (ethylene oxide) with a 5-year shelf life, and intended for multiple use during a single procedure, which is the same as the predicate device (K221006).

Indications for Use:
The GIA™ stapler with Tri-Staple™ technology has applications in abdominal and thoracic surgical procedures for resection, transection and creation of anastomosis.

Technological and Performance Characteristics:
The subject device GIA™ stapler with Tri-Staple™ technology (staple size 2.4mm, 2.7mm, 3.0mm) is substantially equivalent to the predicate device K221006 (staple size 3.0mm, 3.5mm, 4.0mm; 4.0mm, 4.5mm, 5.0mm) regarding the fundamental stapling technologies employed, intended use and indications for use. Both are single-use manual linear staplers.

The Tri-Staple™ technology used in the subject device is exactly the same as the predicate device K221006. The subject disposable manual linear stapler is available in staple size 3.0mm, 3.5mm, 4.0mm; 4.0mm, 4.5mm, 5.0mm, while the predicate device is available in staple size 2.4mm, 2.7mm, 3.0mm. That's why a reference device K221013 offering the similar staple size is to be introduced as control device in performance testing.

Substantial Equivalence:
The subject new product models have the same intended use and indications for use as the predicate device.

They also have the same fundamental scientific technology in that they are all sterile, single use, hand-held, manual surgical instruments equipped with titanium staples intended to have applications in abdominal and thoracic surgical procedures for resection, transection and creation of anastomosis. The subject and predicate device are essentially the same in design and are sterilized via ethylene oxide, but different in staple size.

The below table further summarizes the similarities and differences between the subject and predicate device.

Features	Subject Device	Predicate Device (K221006)	Reference Device (K221013)
	GIA™ Stapler with Tri-Staple™ Technology		GIA™ Stapler with DST Series™ Technology
Manufacturer	Same	Covidien	Covidien
Constructional (example)			
Indications for Use	Same	The GIA™ stapler with Tri-Staple™ technology has applications in abdominal and thoracic surgical procedures for resection, transection and creation of anastomosis.	The GIA™ staplers with DST Series™ technology have applications in abdominal and thoracic surgical procedures for resection, transection and creation of anastomosis.
Operation Method	Same	Manual	Manual
Anatomical Site	Same	Alimentary tract and Thoracic	Alimentary tract and Thoracic
Surgical Approach	Same	Open surgery	Open surgery
Method of Operation	Same	The instruments are activated by sliding the firing knob forward to a complete stop and Immediately after staple formation, the knife blade resects the excess tissue, creating a linear anastomosis.	The instruments are activated by sliding the firing knob forward to a complete stop and Immediately after staple formation, the knife blade resects the excess tissue, creating a linear anastomosis.
Product Codes	Stapler with Cartridge: GIA80TMS, GIA60TMS Cartridge: GIA80TMC, GIA60TMC	Stapler with Cartridge: GIA80MTS, GIA80XTS, GIA60MTS, GIA60XTS Cartridge: GIA80MTC, GIA80XTC, GIA60MTC, GIA60XTC	Stapler with Cartridge: GIA6025S Cartridge: GIA6025L
Staple Rows	Same as predicate device.	3 staggered rows of staples on either side of the tissue cut line with different staple height in each staple row	2 staggered rows of staples on either side of the tissue cut line with same staple height in each staple row
Instrument Handle Type	Same	Single-handle squeeze	Single-handle squeeze

Features	Subject Device	Predicate Device (K221006)	Reference Device (K221013)
	GIA™ Stapler with Tri-Staple™ Technology		GIA™ Stapler with DST Series™ Technology
Staple Cartridge Configuration	Same as predicate device.	2 triple rows staples, step-faced cartridge with different staple size in each staple row	2 staggered rows of staples, flat-faced with same staple height in each staple row
Cartridge Color	Tan	Purple, Black	White
Staple Size (open leg height)	Tan cartridge: 2.4mm, 2.7mm, 3.0mm	Purple cartridge: 3.0mm, 3.5mm, 4.0mm Black cartridge: 4.0mm, 4.5mm, 5.0mm	White cartridge: 2.5mm, 2.5mm
Anvil	Same as predicate device.	2 triple staggered rows of anvil pocket design	2 double staggered rows of anvil pocket design
Staple Line Length	Same as predicate device.	80mm, 60mm	60mm
Staple Material	Same	Titanium per ASTM F67 Grade I	Titanium per ASTM F67 Grade I
Identification of Materials of Implant (staple) and tissue cutting component (knife)	Same	Staple: Titanium per ASTM F67 Grade I Knife: Stainless Steel Anvil: Stainless Steel	Staple: Titanium per ASTM F67 Grade I Knife: Stainless Steel Anvil: Stainless Steel
Biocompatibility	Same as predicate device.	Evaluated per ISO 10993-1 series and FDA biocompatibility guidance	Evaluated per ISO 10993-1 series
Audible Feedback	Same	Yes	Yes
Knife	Same	Yes	Yes
Single Use	Same	Yes	Yes
Disposable	Same	Yes	Yes
Sterile	Same	Ethylene oxide	Ethylene oxide
Shelf Life	Same	5 years	5 years

Tests performed to evaluate and compare technological and performance characteristics:
Non-clinical performance data - the following testing has been performed to demonstrate substantial equivalence to the predicate device.

1. Stability Test for single use device
2. Biocompatibility Test per ISO 10993-1 and FDA guidance “Use of international Standard ISO 10993-1” issued on September 4, 2020
3. Performance Test (In-Vitro)
4. Performance Test (Ex-Vivo)
5. Performance Test (In-Vivo)
6. Performance Test (Chronic)
7. Performance Test (Usability)

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

Conclusion:
Based upon the supporting data summarized above, we concluded that the subject device GIA™ Stapler with Tri-Staple™ Technology is substantially equivalent to the legally-marketed device K221006 and does not raise different questions or additional risks of safety and effectiveness than the predicate device.