March 13, 2020

Covidien
Frank Gianelli
Senior Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K192720
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 13, 2019
Received: September 27, 2019

Dear Frank Gianelli:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192720

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Submission Date: Sep 27, 2019

K192720

SUBMITTER INFORMATION:
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Subject Device:

Proprietary/Trade Name:	GIA™ Stapler with Tri-Staple™ Technology
Model Numbers:	GIA80MTS, GIA80XTS, GIA80MTC, GIA80XTC
Classification Name:	Staple, Implantable
Regulations Number:	21 CFR 878.4750
Product Codes:	GDW
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Staple

Predicate Device:

Proprietary/Trade Name:	GIA™ Stapler with DST™ Technology
510(k) Number:	K111825
Classification Name:	Staple, Implantable
Regulations Number:	21 CFR 878.4750
Product Codes:	GDW
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Staple

Device Description:
The subject 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™ stapler and cartridges with Tri-Staple™ technology are available in 80 mm staple line length and two staple sizes to accommodate various tissue thicknesses: medium/thick and extra thick. Staplers with medium/thick staple size (purple cartridge) deploy three height-progressive

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rows of 3.0 mm, 3.5 mm and 4.0 mm titanium staples on either side of the tissue cut line. Staplers with extra thick staple size (black cartridge) deploy three height progressive rows of 4.0 mm, 4.5 mm and 5.0 mm titanium staples on either side of the cut line. Each GIA™ stapler with Tri-Staple™ technology may be reloaded with GIA™ Cartridge with Tri-Staple™ Technology up to 7 times for a total of 8 firings per instrument.

The subject device GIA™ Stapler with Tri-Staple™ Technology is manufactured with the same patient contact materials that are utilized within the predicate device (K111825).

The subject device GIA™ stapler with Tri-Staple™ technology has the same principle operation as the predicate device. The GIA™ Stapler with Tri-Staple™ Technology is a manual single-use device. It is provided sterile (ethylene oxide) with 5-year shelf life, and intended for multiple use during a single procedure, which is the same as the predicate device (K111825).

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 Characteristics:
The subject new device GIA™ stapler with Tri-Staple™ technology is substantially equivalent to the predicate K111825 GIA™ Stapler with DST™ Technology regarding the fundamental stapling technologies employed, intended use and indications for use. Both are single-use manual linear staplers.

The major technical difference between the subject device GIA™ stapler with Tri-Staple™ technology and predicate device GIA™ Stapler with DST™ Technology is the new proposed device is equipped with Tri-Staple™ Technology.

The subject device GIA™ stapler with Tri-Staple™ technology places two triple staggered row of height progressive titanium staples, hence the name 'Tri-Staple''. The staple line is available in 80mm length. The staplers are offered in 2 cartridge sizes, the purple cartridge deploying three height-progressive rows of 3.0 mm, 3.5 mm and 4.0 mm titanium staples is for medium/thick tissue thickness range and the black cartridge deploying three height progressive rows of 4.0 mm, 4.5 mm and 5.0 mm titanium staples is for extra thick tissue thickness range.

The predicate GIA™ Stapler with DST™ Technology deploy two double staggered same-height rows of titanium staples. The length of the staple line is 80mm. The staplers are offered in 2 cartridge sizes, blue cartridge deploying 2 rows of 3.8mm titanium staples is for medium/thick tissue thickness range, green cartridge deploying 2 rows of 4.8mm titanium staples is for extra thick tissue thickness range.

Substantial Equivalent:
The subject devices have the same intended use and indications for use as the predicate devices.

They are similar in fundamental scientific technology in that they are all sterile, single used, 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 similar in design, materials and are sterilized via ethylene oxide.

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

Features	Subject Device (K192720)	Predicate Device (K111825)
	GIA™ Stapler with Tri-Staple™ Technology	GIA™ Staplers with DST™ Technology
Manufacturer	Covidien	Covidien
Constructional		
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.	The GIA™ staplers with DST™ technology and the knifeless stapler have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.
Operation Method	Manual	Manual
Anatomical Site	Alimentary tract and Thoracic	Alimentary tract and Thoracic
Surgical Approach	Open surgery	Open surgery
Method of Operation	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: GIA80MTS, GIA80XTS Cartridge: GIA80MTC, GIA80XTC	Stapler with Cartridge: GIA8038S, GIA8048S Cartridge: GIA8038L, GIA8048L
Staple Rows	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	Single-handle squeeze	Single-handle squeeze
Staple Cartridge Configuration	2 triple rows staples, step-faced cartridge with different staple size in each staple row	2 double rows staples, flat-faced with same staple size in each staple row
Cartridge Color	Purple, Black	Blue, Green
Staple Size (open leg height)	Purple cartridge: 3.0mm, 3.5mm 4.0mm Black cartridge: 4.0mm, 4.5mm 5.0mm	Blue cartridge: 3.8mm Green cartridge: 4.8mm
Anvil	2 triple staggered rows of anvil pocket design	2 double staggered rows of anvil pocket design
Staple Line Length	80mm	80mm
Staple Material	Titanium per ASTM F67 Grade I	Titanium per ASTM F67 Grade I

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Features	Subject Device (K192720)	Predicate Device (K111825)
	GIA™ Stapler with Tri-Staple™ Technology	GIA™ Staplers with DST™ Technology
Identification of Materials of Implant (staple) and tissue cutting component (knife)	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	Evaluated per ISO 10993-1 series and FDA 2016 biocompatibility guidance	Evaluated per ISO 10993-1 series
Audible Feedback	Yes	Yes
Knife	Yes. without knifeless option	Yes with knifeless option
Single Use	Yes	Yes
Disposable	Yes	Yes
Sterile	Ethylene oxide	Ethylene oxide
Shelf Life	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 devices.

1. Performance Test In-Vitro
   - Visual inspection on product, packaging and instruction for use
   - Staple formation on test media
   - Firing force test
   - Multi-Fire Evaluation

2. Performance Test Ex-Vivo
   - Burst Pressure
   - Pneumostasis
   - Across Staple Line Evaluation

3. Performance Test In-Vivo
   - In vivo safety and efficacy
   - Tissue Abrasion
   - Hemostasis test
   - Staple formation on tissues
   - Chronic survival testing

   Above device testing is completed per FDA Guidance " Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submission" issued on April 26, 2019 on the finial finished sterilized devices that have been subject to all manufacturing processes.

4. Performance Test Human Factors/Usability per IEC 62366 and FDA Guidance 'Applying Human Factors and Usability Engineering to Medical Devices"
   - Human factors evaluation was conducted on the subject device and the predicate device. Based on the results of those studies, the subject device has been found to be

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safe and effective for the intended users, uses and use environments.

5. Biocompatibility testing has been conducted to meet the requirements of ISO 10993-1 and FDA Guidance 'Use of international Standard ISO 10993-1" issued June 16, 2016 on the final manufactured, packaged and sterilized medical device that have been subject to all manufacturing processes.
    - Cytotoxicity test
    - Sensitization
    - Intracutaneous irritation
    - Acute system toxicity
    - Pyrogenicity

6. Sterilization assessment per ISO 11135
    - Overkill method used for validation
    - ETO residual test

7. Stability/Shelf-life studies
    - Accelerated aging test for 5 years shelf life
    - Product and packaging functional test

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