December 7, 2020

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

Re: K202701
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
Dated: November 6, 2020
Received: November 9, 2020

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,

Cindy Chowdhury, Ph.D., M.B.A.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202701

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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510(k) Summary

Date Prepared:
Sep 10, 2020

Submitter:
Leo Chen
Covidien
Rooms 501, 502, 601, 602, No.3 building
No.2388 Chen Hang Road
Min Hang District, Shanghai, 201114, China

Contact:
Katherine Y. Choi (U.S. Agent) on behalf of Leo Chen
Covidien
60 Middletown Avenue
North Haven, CT 06473, USA
Principal Regulatory Affairs Specialist
Telephone: (917) 841-6315
Fax: (203) 492-5029
Email: katherine.y.choi@medtronic.com

Name of Device:

Proprietary/Trade Name:	GIA™ Stapler with Tri-Staple™ Technology
Model Numbers:	GIA60MTS, GIA60XTS, GIA60MTC, GIA60XTC
Classification Name:	Staple, Implantable
Regulations Number:	21 CFR 878.4750
Product Codes:	GDW
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Stapler

Predicate Device:

Proprietary/Trade Name:	GIA™ Stapler with Tri-Staple™ Technology
510(k) Number:	K192720
Classification Name:	Staple, Implantable
Regulations Number:	21 CFR 878.4750
Product Codes:	GDW
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Stapler

Reference Device:

Proprietary/Trade Name:	GIA™ Stapler with DST Series™ Technology
510(k) Number:	K111825
Classification Name:	Staple, Implantable
Regulations Number:	21 CFR 878.4750

Product Codes:	GDW
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Stapler

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 subject GIA™ stapler and cartridges with Tri-Staple™ technology are available in 60 mm staple line length and two staple sizes to accommodate tissue thicknesses: medium/thick and extra thick. Staplers for medium/thick tissue (purple cartridge) deploy three height-progressive rows of 3.0 mm, 3.5 mm and 4.0 mm titanium staples on either side of the tissue cut line. Staplers for extra thick tissue (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 a GIA™ Cartridge with Tri-Staple™ Technology up to 7 times for a total of 8 firings per instrument.

The GIA™ Stapler with Tri-Staple™ Technology is manufactured with essentially the same patient contact materials that are utilized within the predicate device (K192720).

The 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 a 5-year shelf life, and intended for multiple use during a single procedure, which is the same as the predicate device (K192720).

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 line length 60mm) is substantially equivalent to the predicate device K192720 (staple line length 80mm) 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 K192720. The subject disposable manual linear stapler is available in 60mm staple line length, while, the predicate device is available in 80mm staple line length. The 60mm staple line length, however, is not new; the reference device K111825 offers the same length.

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 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 the same in design and are sterilized via ethylene oxide, but different in staple line length.

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

Features	**Subject Device**	**Predicate Device (K192720)**
	GIA™ Stapler with Tri-Staple™ Technology	
Manufacturer	Same as predicate device.	Covidien
Constructional (example)		
Indications for Use	Same as predicate device.	The GIA™ stapler with Tri-Staple™ technology has applications in abdominal and thoracic surgical procedures for resection, transection and creation of anastomosis.
Operation Method	Same as predicate device.	Manual
Anatomical Site	Same as predicate device.	Alimentary tract and Thoracic
Surgical Approach	Same as predicate device.	Open surgery
Method of Operation	Same as predicate device.	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: GIA60MTS, GIA60XTS Cartridge: GIA60MTC, GIA60XTC	Stapler with Cartridge: GIA80MTS, GIA80XTS Cartridge: GIA80MTC, GIA80XTC
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
Instrument Handle Type	Same as predicate device.	Single-handle squeeze
Staple Cartridge Configuration	Same as predicate device.	2 triple rows staples, step-faced cartridge with different staple size in each staple row
Cartridge Color	Same as predicate device.	Purple, Black
Staple Size (open leg height)	Same as predicate device.	Purple cartridge: 3.0mm, 3.5mm, 4.0mm Black cartridge: 4.0mm, 4.5mm, 5.0mm
Anvil	Same as predicate device.	2 triple staggered rows of anvil pocket design
Staple Line Length	60mm Same as reference device (60mm), which is selected to be the control device in the performance testing.	80mm
Staple Material	Same as predicate device.	Titanium per ASTM F67 Grade I

Features	Subject Device	Predicate Device (K192720)
	GIA™ Stapler with Tri-Staple™ Technology	
Identification of Materials of Implant (staple) and tissue cutting component (knife)	Same as predicate device.	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
Audible Feedback	Same as predicate device.	Yes
Knife	Same as predicate device.	Yes.
Single Use	Same as predicate device.	Yes
Disposable	Same as predicate device.	Yes
Sterile	Same as predicate device.	Ethylene oxide
Shelf Life	Same as predicate device.	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. Performance Test (Bench)
    - Visual inspection
    - IFU walkthrough
    - 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)
    - Hemostasis test
    - Staple formation on tissues

4. Biocompatibility Tests per ISO 10993-1 and FDA guidance “Use of international Standard ISO 10993-1” issued on September 4, 2020
    - Cytotoxicity test
    - Sensitization
    - Intracutaneous irritation
    - Acute system toxicity
    - Pyrogenicity

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 K192720 and does not raise different questions or additional risks of safety and effectiveness than the predicate device.