May 5, 2022

Covidien
Angela Arsdale
Senior Manager
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K221013
Trade/Device Name: GIA Auto Suture Stapler with DST Series Technology
Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical Stapler
Regulatory Class: Class II
Product Code: GAG, GDW,
Dated: April 4, 2022
Received: April 5, 2022

Dear Angela 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 (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,

Mark Trumbore
Assistant Director
DHT4A: Division of General 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)*
K221013

Device Name
GIA™ Auto Suture™ Stapler with DST Series™ Technology

Indications for Use *(Describe)*
The reloadable staplers have 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: April 4, 2022

Submitter: Robert Zott
Covidien
60 Middletown Avenue
North Haven, CT 06473
Senior Regulatory Affairs Specialist
Email: robert.zott@medtronic.com

Name of Device:

Proprietary / Trade Name:	GIA™ Auto Suture™ Stapler with DST Series™ Technology
Model Numbers:	GIA10038L, GIA10038S, GIA10048L, GIA10048S, GIA8038L, GIA8038S, GIA8048L, GIA8048S, GIA6025L, GIA6038L, GIA6048L, GIA6025S, GIA6038S, GIA6048S
Classification Name:	Staple, Implantable
Regulation Number:	21 CFR 878.4750 / 21 CFR 878.4740
Product Codes:	GDW / GAG
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™ Auto Suture™ Stapler with DST Series™ Technology
510(k) Number:	K111825
Classification Name:	Staple, Implantable
Regulation 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 with Implantable Staples

Device Description:

The GIA™ Auto Suture™ Stapler with DST Series™ Technology places two double staggered rows of titanium staples and simultaneously cuts and divides the tissue between the two double rows. The staplers and accompanying single use loading units (SULUs, also referred to as "reloads") are available in 60 mm, 80 mm, and 100 mm lengths. Three staple sizes are available: 2.5 mm, 3.8 mm, and 4.8 mm to accommodate varying tissue thicknesses. The GIA™ stapler may be reloaded with a GIA™ Auto Suture™ Loading Unit with DST Series™ Technology up to 7 times for a total of 8 firings per instrument.

Indications for Use:

The reloadable staplers have applications in abdominal and thoracic surgical procedures for resection, transection and creation of anastomosis.

Technological and Performance Characteristics:

The sled inside of the single use loading unit (SULU), as it travels down the channel along its center, will strike the staple pusher components which, in turn, will push the titanium staples out of the cartridge and through the target tissue with the open legs of the staples striking the anvil of the reload to form B-shaped staples in the tissue. While this action is occurring, the knife bar, as it advances down the reload channel, will divide the tissue between the staple lines that are being formed resulting in two staple lines on either side of the cut line. Directional Stapling Technology (DST™) is a proprietary technology that provides consistent and reliable staple formation by reducing the potential for the staple to twist.

Substantial Equivalence:

The subject device is substantially equivalent in terms of previously-cleared indications, intended use, device design, and the fundamental stapling technology employed. There has been no change in operating principle. Both devices are sterile, single-use, hand-held, manual surgical instruments equipped with titanium staples. The patient contact materials of the subject and predicate devices are substantially equivalent; both are Ethylene Oxide (EtO) sterilized with a 5-year shelf life, and both can be fired up to 8 times during a single procedure.

With regard to the previously-cleared indications, the subject device described herein is the version containing a knife blade. Gynecologic, pediatric and pancreatic indications have not been included in this premarket notification.

The Substantial Equivalence Overview Table below summarizes the substantial equivalence between the subject and predicate devices.

Substantial Equivalence Overview Table

Features	Subject Device GIA™ Auto Suture™ Stapler with DST Series™ Technology	Predicate Device (K111825) GIA™ Auto Suture™ Stapler with DST Series™ Technology
Manufacturer	Same as predicate device.	Covidien
Construction		
Indications for Use & Intended Use	The reloadable staplers have applications in abdominal and thoracic surgical procedures for resection, transection and creation of anastomosis.	The DST Series™ GIA™ Staplers and the DST Series™ SGIA™ Knifeless Stapler have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis. The SGIA™ Knifeless stapler may be used for occlusion of the left atrial appendage in open procedures. They may be used for transection and resection of pancreas.
Contra-indications	The Contraindication has been modified as follows: "The instrument should not be used on tissues that are necrotic, friable, or have altered integrity, e.g., ischemic or edematous tissues."	The IFU in the predicate submission states the following in the Contraindications: "The DST Series™ GIA™ Stapler instruments should not be used on friable or delicate tissue and/or where the closure of the device might be destructive to the tissues."
Warnings, Precautions, and Instructions for Use	Various labeling edits and additions based on the Stapling Guidance.	The predicate labeling was cleared prior to the issuance of the Labeling Guidance.
Anatomical Site	Same as predicate device.	Alimentary Tract Thoracic
Surgical Approach	Same as predicate device.	Open Surgery
Method of Operation	Same as predicate device.	The instrument is activated by sliding the firing knob forward to a complete stop. Immediately following staple formation, the knife blade resects the excess tissue.

Features	Subject Device GIA™ Auto Suture™ Stapler with DST Series™ Technology	Predicate Device (K111825) GIA™ Auto Suture™ Stapler with DST Series™ Technology
Product Codes	GIA10038L, GIA10038S, GIA10048L, GIA10048S, GIA8038L, GIA8038S, GIA8048L, GIA8048S, GIA6025L, GIA6038L, GIA6048L, GIA6025S, GIA6038S, GIA6048S	GIA10038L, GIA10038S, GIA10048L, GIA10048S, GIA8038L, GIA8038S, GIA8048L, GIA8048S, GIA6025L, GIA6038L, GIA6048L, GIA6025S, GIA6038S, GIA6048S, SGIA6038L, SGIA6038S
Staple Rows	Same as predicate device.	Two staggered rows of staples on either side of the tissue cut line.
Instrument Handle	Same as predicate device.	Handle is manually squeezed while the firing knob is pushed forward.
Staple Cartridge Configuration	Same as predicate device.	Two double rows of staples.
Cartridge Color & Open Staple Heights	Same as predicate device.	White (2.5 mm), Blue (3.8 mm), Green (4.8 mm)
Anvil	Same as predicate device.	Two double staggered rows of anvil pocket design.
Staple Line Length	Same as predicate device.	60 mm, 80 mm, and 100 mm
Identification of Materials of Implant (staple) and tissue cutting component (knife)	Same as predicate device.	Staple: Titanium per ASTM F67 Grade I Anvil & Knife: Stainless Steel
Biocompatibility	Evaluated per ISO 10993-1 series and the FDA biocompatibility guidance.	Evaluated per ISO 10993-1 series.
Audible Feedback	Same as predicate device.	Audible click heard upon closure of the device.
Knife	Same as predicate device.	Yes.
Single Use	Same as predicate device.	Yes

Features	Subject Device GIA™ Auto Suture™ Stapler with DST Series™ Technology	Predicate Device (K111825) GIA™ Auto Suture™ Stapler with DST Series™ Technology
Disposable	Same as predicate device.	Yes
Sterile	Same as predicate device.	Ethylene Oxide (EtO)
Shelf Life	Same as predicate device.	5 years

Testing Performed:

The following non-clinical testing was performed to evaluate the labeling changes summarized in this Special 510(k).

1. Usability Evaluation of Labeling Changes in accordance with IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices;

2. Staple Line Reinforcement Material Evaluation (Ex-Vivo).

No clinical study has been deemed necessary since substantial equivalence has been sufficiently demonstrated by non-clinical studies.

Conclusion:

Based on the supporting data summarized above, Covidien has concluded that the subject device GIA™ Auto Suture™ Stapler with DST Series™ Technology is substantially equivalent to the legally-marketed predicate device K111825 and does not raise different questions or risks regarding safety and effectiveness.