August 16, 2023

Covidien
Emily Jacobs
Principal Biomedical Engineer
60 Middletown Ave.
North Haven, Connecticut 06473

Re: K231491
Trade/Device Name: TA™ Stapler and Loading Unit with DST Series™ Technology
Regulation Number: 21 CFR 878.4740
Regulation Name: Stapler, Surgical
Regulatory Class: Class II
Product Code: GAG, GDW
Dated: May 23, 2023
Received: May 23, 2023

Dear Emily Jacobs:

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 and Part 809); 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 -S

Digitally signed by Mark Trumbore -S
Date: 2023.08.16 13:45:53 -04'00'

Mark Trumbore, Ph.D.
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team
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

IFU

INDICATIONS FOR USE:
The TA™ Stapler with DST Series™ technology is indicated for use in abdominal and thoracic surgical procedures for transection or resection of tissue.
The intended purpose of the device is the application of staples for the purpose of tissue approximation and is limited to the aspect of stapling the tissue to prepare for the transection and resection of tissue.

510(k) Summary

DATE PREPARED:
May 23rd, 2023

SUBMITTER:
Covidien
60 Middletown Avenue
North Haven, CT 06473 USA

CONTACT PERSON:
Emily E. Jacobs, Ph.D.
Principal Biomedical Engineer
Telephone: (203) 492-8433

IDENTIFICATION OF DEVICE:

Proprietary/Trade Name:	TA™ Stapler with DST Series™ Technology
Classification Name:	Staples, Implantable
Regulation Number:	21 CFR 878.4740
Device Class:	Class II
Product Code:	GAG (Primary), GDW (Secondary)
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Stapler

PREDICATE DEVICE:

	Predicate
510(k) Number	K111825 (Oct 25, 2011)
Proprietary/Trade Name	TA™ Staplers with DST Series™ Technology and TA™ Loading Units with DST Series™ Technology
Classification Name	Staple, Implantable
Regulation Number	21 CFR 878.4750
Device Class	Class II
Product Code	GDW
Review Panel	General and Plastic Surgery
Common Name	Surgical Stapler

DEVICE DESCRIPTION:
The TA™ Stapler with DST Series™ Technology with a TA™ Loading Unit with DST Series™ Technology is a modular stapling system indicated for use during transection and resection of tissue during surgical procedures.

The TA™ Stapler is a handheld mechanical stapler handle used to position and deploy TA™ Loading Units, which are staple cartridges containing titanium staples. The TA™ staplers and TA™ Loading Units are supplied sterile. To perform its intended use, the distal shaft of a TA™ Stapler is assembled with a TA™ loading unit. The TA™ Stapler acts as a stapler handle used by the surgeon to insert and position the TA™ Loading Units inside the body via an incision. The TA™ Loading Unit is then mechanically activated by the surgeon by squeezing the handle of the TA™ stapler, thereby deploying staggered rows of titanium staples to close incisions in abdominal and thoracic tissue. The TA™ Stapler is reloadable meaning the surgeon can manually remove a fired TA™ Loading Unit and replace it with a new TA™

Loading Unit for subsequent firing in a single patient surgical procedure. The TA™ Stapler can be reloaded up to 7 times for a total of 8 firings per instrument.

The TA™ Staplers with DST Series™ Technology are available with staple line anvil lengths that accommodate 30, 45, 60 and 90 mm length TA™ Loading Units. The TA™ Loading Unit with DST Series™ Technology are available with staple heights of 2.5 mm (white vascular cartridge, 3 rows of staples, 30 mm length only); 3.5 mm (blue cartridge, 2 rows of staples, 30, 45, 60 and 90 mm lengths); 4.8 mm (green cartridge, 2 rows of staples, 30, 45, 60 and 90 mm lengths).

The TA™ Loading Unit with DST Series™ Technology and TA™ Staplers with DST Series™ Technology are intended to be used by medical professionals qualified in the transportation, preparation, and use of surgical devices. The TA™ Loading Unit with DST Series™ Technology and TA™ Staplers with DST Series™ Technology are intended for use in a sterile operating room environment in surgical procedures where surgical stapling is indicated.

No significant design improvements or changes have been implemented since the predicate K111825, however the indication of use has been updated.

This submission also addresses the new requirements applicable to the surgical stapler under FDA's Final Order 2021-22041 and the new FDA's guidance titled "Surgical Staplers and Staples for Internal use – Labeling Recommendations." (Issued on October 8, 2021). New performance testing has been conducted and included to ensure data reflects the currently manufactured and marketed device.

INDICATIONS FOR USE:
The TA™ Stapler with DST Series™ technology is indicated for use in abdominal and thoracic surgical procedures for transection or resection of tissue.

The intended purpose of the device is the application of staples for the purpose of tissue approximation and is limited to the aspect of stapling the tissue to prepare for the transection and resection of tissue.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:
The TA™ Loading Unit with DST Series™ Technology and TA™ Staplers with DST Series™ Technology are identical to their predicate K111825. No significant design improvements or changes have been made. Key design features such as staple design, staple material, number of staggered staple rows, staple sizes available, stapler handle design and deployment mechanism, and indicated tissue thickness ranges have all remained the same as the predicate.

SUBSTANTIAL EQUIVALENCE:
The TA™ Loading Unit with DST Series™ Technology and TA™ Staplers with DST Series™ Technology are identical to their predicate K111825. No significant design improvements or changes have been made. This submission's purpose is to address the new requirements applicable to the surgical stapler under FDA's Final Order 2021-22041 and the new FDA's guidance titled "Surgical Staplers and Staples for Internal use – Labeling Recommendations." (Issued on October 8, 2021) and provide updated performance testing reflective of the current manufactured and marketed device.

SUMMARY OF STUDIES:
Non-clinical performance data – The following studies have been performed to demonstrate substantial equivalence and ensure compliance with the new requirements applicable to the surgical stapler under FDA's Final Order 2021-22041 and the new FDA's guidance titled "Surgical Staplers and Staples for Internal use – Labeling Recommendations." (Issued on October 8, 2021):

- Performance testing per 21 CFR 878.4740 (b)(2)(i) such as (A) bench top, *ex-vivo, and in-vivo* pre-clinical testing to evaluate staple formation characteristics in maximum and minimum tissue thickness, (B) measurement of the worst-case deployment pressure of stapler firing force, (C) measurement of staple line strength, and (D) conformation of staple line integrity
- Acute GLP study performed to evaluate the (E) *in-vivo* conformation of staple line hemostasis and integrity

To ensure compliance with the new requirements applicable to the surgical stapler under FDA's Final Order 2021-22041 and the new FDA's guidance titled "Surgical Staplers and Staples for Internal use – Labeling Recommendations." (Issued on October 8, 2021), the following supporting data has been included. When possible, applicable FDA-recognized standards were considered:

- Biocompatibility evaluation conducted in accordance with the FDA's 2020 guidance and ISO 10993-1
- Shelf life/packaging stability
- Usability

MR safety information was not part of K111825; therefore, new testing has been performed per the latest FDA Guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" issued on May 20, 2021, and labeling has been updated.

Previously demonstrated compliance for the following aspects remains unimpacted:

- Ethylene oxide (EO) sterilization validation for the single use devices with a minimum Sterility Assurance Level (SAL) of 10^{-6}

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

CONCLUSION:

Based upon the supporting data summarized above, we concluded that the TA™ Staplers with DST Series™ Technology, when used with the TA™ Loading Unit with DST Series™ Technology, are as safe and effective as the legally marketed predicate device, and do not raise different questions of safety and effectiveness than the predicate device.