January 23, 2020

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

Re: K192330
Trade/Device Name: EEA Circular Stapler with Tri-Staple Technology
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: December 16, 2019
Received: December 19, 2019

Dear Mr. 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: 08/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192330

Device Name

EEA™ Circular Stapler with Tri-Staple™ Technology

Indications for Use *(Describe)*

The EEA™ circular stapler with Tri-Staple™ technology has application throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

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:
January 20, 2020

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Name of Device:

Proprietary/Trade Name:	EEA™ Circular Stapler with Tri-Staple™ Technology (Black)
Model Numbers:	TRIEEA28XT, TRIEEA31XT, TRIEEA33XT, TRIEEAXL28XT, TRIEEAXL31XT, TRIEEAXL33XT
Classification Name:	Staple, Implantable
Regulations Number:	21 CFR 878.4750
Product Codes:	GDW, GAG
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Stapler

Predicate Devices:

Primary Predicate Device:

Proprietary/Trade Name:	EEA™ Circular Stapler with Tri-Staple™ Technology (Purple)
510(k) Number:	K172361
Classification Name:	Staple, Implantable
Regulations Number:	21 CFR 878.4750
Product Codes:	GDW, GAG
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Stapler

Additional Predicate Device:

Proprietary/Trade Name:	EEA™ Circular Stapler with DST Series™ Technology
510(k) Number:	K062850
Classification Name:	Staple, Implantable

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

Device Description:
The EEA™ circular stapler with Tri-Staple™ technology (Black) places a circular, triple staggered row of titanium staples and resects the excess tissue, creating a circular anastomosis as an end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries. The instrument is activated by squeezing the handle firmly as far as it will go. The subject circular stapler will be offered for an extra thickness range, which is identified by the black staple guide. Staplers with extra thick staple size deploy three height progressive rows of 4.0 mm, 4.5 mm and 5.0 mm titanium staples. The subject circular staplers are available in 3 lumen sizes 28, 31, 33mm and 2 shaft lengths a standard 22 cm shaft and an XL 35 cm shaft. The Tilt-Top™ anvil is available on all staplers. A blunt tipped anvil trocar accessory is provided to assist in introducing the anvil into the surgical field.

The EEA™ Circular Stapler with Tri-Staple™ Technology (Black) is manufactured with patient contact materials (stainless steel, titanium) that are utilized within the predicate devices (K172361 and K062850).

The EEA™ Circular Stapler with Tri-Staple™ Technology (Black) is a manual device which is utilized by approximating tissue, instrumentation activation by squeezing the handle firmly as far as it will go, audible and tactile firing indicator upon completion of the staple firing and removal of the device from the surgical field in the same manner as the predicate devices (K172361 and K062850).

The EEA™ Circular Stapler with Tri-Staple™ Technology (Black) is a single-use device that is packaged and sterilized via ETO (Ethylene Oxide) with a 5-year shelf life, which is the same as the predicate devices (K172361 and K062850).

Indications for Use:
The EEA™ Circular Stapler with Tri-Staple™ Technology (Black) has application throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

Technological Characteristics:
The subject new devices EEA™ circular stapler with Tri-Staple™ technology (Black) are substantially equivalent to primary predicate device K172361 EEA™ Circular Stapler with Tri-Staple™ Technology (Purple) and the additional predicate device K062850 EEA™ circular stapler with DST Series™ technology regarding the fundamental stapling technologies employed, intended use and indications for use. All of them are single-use manual circular staplers that have application throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

The Tri-Staple™ technology used in the subject devices are fundamentally the same as the primary predicate device K172361 with the exception that the subject devices deploy 3 height progressive rows of 4.0 mm, 4.5 mm and 5.0 mm titanium staples for use in extra thick tissue applications and is identified by the black staple guide. Conversely, the primary predicate devices

deploy 3 height progressive rows of 3.0 mm, 3.5 mm and 4.0 mm titanium staples for use in medium/thick tissue applications and is identified by the purple staple guide. That's why an additional predicate offering for an extra thick tissue thickness is introduced as control device in performance testing.

The additional predicate device K062850 EEA™ circular stapler with DST Series™ technology deploy 2 staggered rows of 4.8mm staples, for use in extra thick tissue thickness range similar to the subject device. A series of comparison testing has been conducted between the subject new devices and the additional predicate devices and is provided in this submission.

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 be used during open or laparoscopic surgical procedures of the alimentary tract, to create anastomoses (end-to-end, end-to-side, or side-to-side) via intraluminal (within the lumen) resection. The subject and predicate devices are similar in design, materials and are sterilized via ethylene oxide.

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

Features	**Subject Device**	**Primary Predicate Device (K172361)**	**Additional Predicate Device (K062850)**
	EEA™ Circular Stapler with Tri-Staple™ Technology (Black)	EEA™ Circular Stapler with Tri-Staple™ Technology (Purple)	EEA™ Circular Stapler with DST Series™ Technology
Manufacturer	Covidien	Covidien	Covidien
Constructional			
Indications for Use	The EEA™ Circular Stapler with Tri-Staple™ Technology has application throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.	The EEA™ Circular Stapler with Tri-Staple™ Technology has application throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.	The EEA™ Circular Stapler with DST Series™ Technology has application throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.
Operation Method	Manual	Manual	Manual
Anatomical Site	Alimentary tract	Alimentary tract	Alimentary tract
Surgical Approach	Open and laparoscopic	Open and laparoscopic	Open and laparoscopic
Staple Rows	3 staggered rows of staples with different staple height in each staple row	3 staggered rows of staples with different staple height in each staple row	2 staggered rows of staples with same staple height in each staple row

Features	Subject Device	Primary Predicate Device (K172361)	Secondary Predicate Device (K062850)
	EEA™ Circular Stapler with Tri-Staple™ Technology (Black)	EEA™ Circular Stapler with Tri-Staple™ Technology (Purple)	EEA™ Circular Stapler with DST Series™ Technology
Staple Guide Color	Black	Purple	Green
Staple Size (open leg height)	4.0mm, 4.5mm 5.0mm	3.0mm, 3.5mm, 4.0mm	4.8mm, 4.8mm
Staple Material	Titanium per ASTM F67 Grade I	Titanium per ASTM F67 Grade I	Titanium per ASTM F67 Grade I
Lumen Sizes	28mm/31mm/33mm	28mm/31mm/33mm	28mm/31mm/33mm
Stapler Length	Standard length: 22cm Extra length XL: 35cm	Standard length: 22cm Extra length XL: 35cm	Standard length: 22cm Extra length XL: 35cm
Audible Feedback	Yes	Yes	Yes
Anvil Head	3 staggered rows of anvil bucket, lipless design	3 staggered rows of anvil bucket, lipless design	2 staggered rows of anvil bucket, lipped design
Safety Lever	Red color	Red color	White color
Key Parts Materials	Knife: Stainless Steel Anvil: Stainless Steel Tube: Aluminum	Knife: Stainless Steel Anvil: Stainless Steel Tube: Aluminum	Knife: Stainless Steel Anvil: Stainless Steel Tube: Aluminum
Biocompatibility	Evaluated per ISO 10993-1 series and FDA 2016 biocompatibility guidance	Evaluated per ISO 10993-1 series and FDA 2016 biocompatibility guidance	Evaluated per ISO 10993-1 series
Single Use	Yes	Yes	Yes
Disposable	Yes	Yes	Yes
Sterile	Ethylene oxide	Ethylene oxide	Ethylene oxide
Shelf Life	5 years	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
    - Safety lock release force test
    - Staple formation on test media
    - Anvil attach force test
    - Anvil detach force test
    - Clamping force test
    - Unclamping force test
    - Firing force test

    The acceptance criteria of each test within the In-Vitro section has been satisfied and results deemed acceptable.

2. Performance Test _ Ex-Vivo
    - EX-Vivo Firings
    - Knife cut evaluation
    - Leak / Burst test

All units evaluated yielded comparable or better results in accordance with the acceptance criteria for Ex-Vivo test, which demonstrate the substantial equivalence of the subject devices as compared to the predicate device.

3. Performance Test _ In-Vivo Study
    - Atraumatic tissue test
    - Hemostasis test
    - Staple formation on tissues
    - Chronic survival study

    All units evaluated yielded comparable or better results in accordance with the acceptance criteria for In-Vivo acute test, which demonstrate the substantial equivalence of the subject devices as compared to the predicate device.

    The chronic animal study performed to evaluate the performance of the subject device and predicate device shows no differences in healing metrics or anastomotic index.

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 devices. This testing report has been included in the predicate submission (K172361).
    - The usability testing validated the performance of the device meets identified user needs and intended use; validated potential use errors identified which have been mitigated through the product design or instruction; validate training and instruction via the proposed device Instruction for Use on device operation.
    - The results of the testing demonstrate the substantial equivalence of the subject devices as compared to the predicate device.

5. Biocompatibility tests per ISO 10993-1 and FDA guidance “Use of international Standard ISO 10993-1” issued June 16, 2016
    - Cytotoxicity test
    - Sensitization
    - Intracutaneous irritation
    - Acute system toxicity
    - Pyrogenicity

    The biocompatibility test results support the subject devices are biocompatible.

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

    The sterilization validation demonstrates the sterilization cycle used for the single use devices can effectively achieve a minimum Sterility Assurance Level (SAL)of 10^{-6}.

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

    The stability study results support a 5-year shelf life of the single use devices.

8. 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 intended use, technological characteristics and supporting performance data summarized above, we concluded that the new subject devices EEA™ Circular Stapler with Tri-Staple™ Technology are substantially equivalent to the legally-marketed predicate devices K172361 and K062850.