November 30, 2022

Covidien
Leo Chen
Principal Regulatory Affairs Specialist
Rooms 501, 502, 601, 602, No.3 building
No.2388 Chen Hang Road
Shanghai,
China

Re: K221771
Trade/Device Name: EEA Circular Stapler with Tri-Staple Technology
Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical Stapler
Regulatory Class: Class II
Product Code: GAG, GDW
Dated: October 28, 2022
Received: November 4, 2022

Dear Leo Chen:

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 -S

Digitally signed by Mark Trumbore -S
Date: 2022.11.30 15:32:48 -05'00'

Mark Trumbore, PhD
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K221771

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.

510(k) Summary

K221771

Date Prepared:
Nov 28, 2022

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Name of Device:

Proprietary/Trade Name:	EEA™ Circular Stapler with Tri-Staple™ Technology
Model Numbers:	TRIEEA21MT, TRIEEA21XT, TRIEEAXL21MT, TRIEEAXL21XT
Classification Name:	Stapler, Surgical; Staple, Implantable
Regulations Number:	21CFR 878.4740, 21 CFR 878.4750
Product Codes:	GAG, GDW
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical stapler with implantable staples

Primary Predicate Device:

Proprietary/Trade Name:	EEA™ Circular Stapler with Tri-Staple™ Technology
510(k) Number:	K202507
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 with implantable staples

Secondary Predicate Device:

Proprietary/Trade Name:	EEA™ Circular Stapler with Tri-Staple™ Technology
510(k) Number:	K221005

Classification Name:	Stapler, Surgical; Staple, Implantable
Regulations Number:	21CFR 878.4740, 21 CFR 878.4750
Product Codes:	GAG, GDW
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical stapler with implantable staples

Reference 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 with implantable staples

Device Description:

The EEA™ circular stapler with Tri-Staple™ technology places a circular, triple staggered row of titanium staples and resects the excess tissue, creating a circular anastomosis. The instrument is activated by squeezing the handle firmly as far as it will go. The subject circular stapler is available in 21mm lumen size and 2 shaft lengths; a standard 22 cm shaft and an XL 35 cm shaft. The staplers are offered in 2 staple sizes, medium/thick and extra thick. Staplers with medium/thick staple size (purple) deploy three height-progressive rows of 3.0 mm, 3.5 mm and 4.0 mm titanium staples. Staplers with extra thick staple size (black) deploy three height-progressive rows of 4.0 mm, 4.5 mm and 5.0 mm titanium staples. The low profile Tilt-Top™ anvil is available on all staplers. A blunt and a sharp tipped anvil trocar accessory is provided to assist in introducing the anvil into the surgical field.

Both the subject device and the predicate device (K202507 and K221005) are from the same product family Tri-Staple™ EEA™ stapler. The subject device EEA™ Circular Stapler with Tri-Staple™ Technology (lumen size 21mm) provides the surgeons a choice of additional lumen size selection to best suit the target anatomy.

The subject EEA™ Circular Stapler with Tri-Staple™ Technology is manufactured with the same patient contact materials that are utilized within the predicate device (K202507 and K221005).

In the same manner as the predicate device (K202507 and K221005), the subject EEA™ Circular Stapler with Tri-Staple™ Technology is a manual surgical stapling device that places a circular, triple staggered row of titanium staples and resects the excess tissue, creating a circular anastomosis. The instrument is activated by squeezing the handle firmly as far as it will go. An audible and tactile firing indicator will provide additional feedback of firing completion.

The subject EEA™ Circular Stapler with Tri-Staple™ Technology 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 device (K202507 and K221005).

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.

Technological and Performance Characteristics:
The subject device EEA™ circular stapler with Tri-Staple™ technology (lumen size 21mm) is substantially equivalent to the predicate device K202507 and K221005 (lumen sizes 25mm, 28mm, 31mm and 33mm) regarding the fundamental stapling technologies employed, intended use and indications for use. All EEA™ circular staplers with Tri-Staple™ technology 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 device is fundamentally the same as the predicate device K202507 and K221005. The subject circular staplers are available in 21mm lumen size, meanwhile, the predicates are available in 4 lumen sizes 25mm, 28mm, 31mm and 33mm. That's why a reference device K062850 offering 21mm lumen size is to be introduced as control device in performance testing.

Substantial Equivalent:
The subject new product models have the same intended use and indications for use as the predicate device.

They are same in fundamental scientific technology in that they are all sterile, single use, 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 same in design, materials and are sterilized via ethylene oxide, but different in lumen size.

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

Features	**Subject Device K221771**	**Predicate Device**		**Reference Device K062850**
		K202507	**K221005**	
	EEA™ Circular Stapler with Tri-Staple™ Technology			EEA™ Circular Stapler with DST Series™ Technology
Manufacturer	Same as predicate device.	Covidien		Covidien
Indications for Use	Same as predicate device.	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	Same as predicate device.	Manual		Manual

Features	Subject Device K221771	Predicate Device		Reference Device K062850
		K202507	K221005	
	EEA™ Circular Stapler with Tri-Staple™ Technology			EEA™ Circular Stapler with DST Series™ Technology
Anatomical Site	Same as predicate device.	Alimentary tract		Alimentary tract
Surgical Approach	Same as predicate device.	Open and laparoscopic		Open and laparoscopic
Staple Rows	Same as predicate device.	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
Staple Guide Color	Same as predicate device.	Black Purple		Aqua (21mm)
Staple Size (open leg height)	Same as predicate device.	Black staple guide: 4.0mm,4.5mm,5.0mm Purple staple guide: 3.0mm,3.5mm,4.0mm		Aqua (21mm): 4.8mm, 4.8mm 3.5m, 3.5mm
Lumen Sizes	21mm Same as reference device (21mm), which is selected to be the control device in the performance testing.	25mm	25mm/28mm/31mm/33mm	21mm
Staple Material	Same as predicate device.	Titanium per ASTM F67 Grade I		Titanium per ASTM F67 Grade I
Stapler Length	Same as predicate device.	Standard length: 22cm Extra length XL: 35cm		Standard length: 22cm Extra length XL: 35cm
Audible Feedback	Same as predicate device.	Yes		Yes
Anvil Head	Same as predicate device.	3 staggered rows of anvil bucket, lipless design		2 staggered rows of anvil bucket, lipped design
Safety Lever	Same as predicate device.	Red color		White color
Key Parts Materials	Same as predicate device.	Knife: Stainless Steel Anvil: Stainless Steel Tube: Aluminum		Knife: Stainless Steel Anvil: Stainless Steel Tube: Aluminum
Biocompatibility	Same as predicate device.	Evaluated per ISO 10993-1 series and FDA biocompatibility guidance		Evaluated per ISO 10993-1 series
Single Use	Same as predicate device.	Yes		Yes
Disposable	Same as predicate device.	Yes		Yes
Sterile	Same as predicate device.	Ethylene oxide		Ethylene oxide
Shelf Life	Same as predicate device.	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 device.

1. Performance Test (In-Vitro)
   - Visual/Packaging Inspection
   - IFU Walkthrough
   - Safety Lock Release Force Test
   - Staple Formation on Test Medium
   - Anvil Retention Force Test
   - Anvil Attach Force Test
   - Anvil Detach Force Test
   - Clamping Force Test
   - Unclamping Force Test
   - Firing Force Test

2. Performance Test (Ex-Vivo)
   - Ex-Vivo Firings
   - Knife Cut Evaluation
   - Leak / Burst Test

3. Performance Test (In-Vivo)
   - Atraumatic Tissue Test
   - Hemostasis Test
   - Staple Formation on Tissues

4. Performance Test (Chronic)
   Chronic animal study performed to evaluate the performance of the subject device and the reference device shows no differences in healing metrics or anastomotic index, and the results demonstrate that the acceptance criteria were met.

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 EEA™ Circular Stapler with Tri-Staple™ Technology is substantially equivalent to the legally-marketed device (K202507 and K221005) and does not raise different questions or additional risks of safety and effectiveness than the predicate device.