April 29, 2022

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

Re: K221005
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: March 30, 2022
Received: April 5, 2022

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,

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)*
K221005

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared:
Apr 21, 2022

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

US Contact:
Katherine Y. Choi
Covidien
60 Middletown Avenue
North Haven, CT 06473, USA
Senior Principal Regulatory Affairs Specialist
Email: katherine.y.choi@medtronic.com

Name of Device:

Proprietary/Trade Name:	EEA™ Circular Stapler with Tri-Staple™ Technology
Model Numbers:	TRIEEA25MT, TRIEEA25XT, TRIEEAXL25MT, TRIEEAXL25XT, TRIEEA28MT, TRIEEA28XT, TRIEEAXL28MT, TRIEEAXL28XT, TRIEEA31MT, TRIEEA31XT, TRIEEAXL31MT, TRIEEAXL31XT, TRIEEA33MT, TRIEEA33XT, TRIEEAXL33MT, TRIEEAXL33XT
Classification Name:	Staple, Implantable; Stapler, Surgical
Regulations Number:	21 CFR 878.4750, 21CFR 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:	EEA™ Circular Stapler with Tri-Staple™ Technology
Model Numbers:	TRIEEA25MT, TRIEEA25XT, TRIEEAXL25MT, TRIEEAXL25XT, TRIEEA28MT, TRIEEA28XT, TRIEEAXL28MT, TRIEEAXL28XT, TRIEEA31MT, TRIEEA31XT, TRIEEAXL31MT, TRIEEAXL31XT, TRIEEA33MT, TRIEEA33XT, TRIEEAXL33MT, TRIEEAXL33XT
510(k) Number:	K202507 (Primary Predicate Device) K192330, K172361
Classification Name:	Staple, Implantable
Regulations Number:	21 CFR 878.4750
Product Codes:	GDW / GDW / 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 as an end-to-end, end-to-side or side-to-side anastomosis in both open and laparoscopic surgeries. The instrument is activated by squeezing the handle firmly as far as it will go. The diameter of the staple line is determined by the selection of the 33 mm, 31 mm, 28 mm, 25 mm stapler. The EEA™ circular stapler with Tri-Staple™ technology is available in 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 (only applicable to 25mm stapler) tipped anvil trocar accessory is provided to assist in introducing the anvil into the surgical field.

The design modification is to add one contraindication per special control 21 CFR 878.4740(b)(2)(ix)(A), and revises IFUs and labels per new regulation requirements.

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 EEA™ Circular Stapler with Tri-Staple™ Technology with a new contraindication does not change the fundamental operating principle and mechanism of action when compared to the predicate device. This Special 510(k) submission is triggered by the addition of a contraindication called for in the Labeling Guidance: a statement noting that the device “should not be used to staple tissues that are necrotic, friable, or have altered integrity, e.g., ischemic or edematous tissues.” This contraindication is consistent with surgical training and practice. All EEA™ circular staplers with Tri-Staple™ technology are single-use manual circular staplers.

Substantial Equivalent:
The subject device with a new contraindication is substantially equivalent to the legally marketed EEA™ Circular Stapler with Tri-Staple™ Technology (K202507, K192330, K172361). The intended use, or indications of the subject device is not altered with the introduction of new contraindication.

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.

Summary of Studies:
Non-clinical performance data – Usability assessment was performed for the proposed labeling changes to demonstrate substantial equivalence to the predicate device.

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 with a new contraindication is substantially equivalent to the legally-marketed device K202507, K192330, K172361 and does not raise different questions or additional risks of safety and effectiveness than the predicate device.