February 16, 2018

Covidien
Sarah Tang
Sr. Regulatory Affair Specialist
Rooms 501, 502, 601, 602 No.3 building
No.2388, Chen Hang Road
Min Hang District, Shanghai, 201114 Cn

Re: K172361
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: August 2, 2017
Received: August 4, 2017

Dear Sarah Tang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

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 per 21 CFR 807.92

Date Prepared:

February 14, 2018

Submitter:

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

Contact:

Frank Gianelli (U.S. Agent) on behalf of Sarah Tang
Senior Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, CT 06473
U.S.A
Office 203.492.5352 | Fax 203.492.5029 | Email frank.gianelli@medtronic.com

Name of Device:

Trade/Proprietary Name: EEA™ Circular Stapler with Tri-Staple™ Technology
Model Numbers: TRIEEA28MT, TRIEEA31MT, TRIEEAXL33MT
Classification Name: Surgical Stapler with Implantable Staples Classification (21 CFR 878.4750) Regulation Name: Implantable Staple
Panel Number: 79
Product Code: GDW, Class: II

Predicate Device:

Trade/Proprietary Name: EEA™ Circular Stapler with DST Series™ Technology
Common Name: Surgical Stapler with Implantable Staples Classification
Product Code, Regulation: GDW, 21 CFR 878.4750 / GAG, 21 CFR 878.4800
510(k) Number: K062850
Class: II
Manufacturer: Covidien

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 diameter of the staple line is 33 mm, 31 mm, 28 mm. 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 one staple size medium/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. The low profile 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 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 EEA™ Circular Stapler with Tri-Staple™ Technology is a manual single-use device that is packaged and sterilized via ETO (Ethylene Oxide) with a 5-year shelf life.

The EEA™ Circular Stapler with Tri-Staple™ Technology is designed for prescription use only per 21 CFR 801 Subpart D. The device is utilized in open and laparoscopic surgical procedures.

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

The EEA™ Circular Stapler with Tri-Staple™ Technology 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 device (K062850).

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:

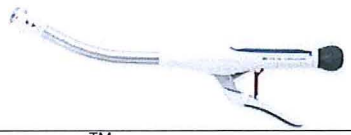
The EEA™ circular stapler with Tri-Staple™ technology is substantially equivalent to the predicate EEA™ Circular Stapler with DST Series™ Technology in regard to the fundamental stapling technologies employed. The proposed device EEA™ Circular Stapler with Tri-Staple™ Technology places a circular, triple staggered row of titanium staples and resects the tissue, creating a circular anastomosis.

The EEA™ circular stapler with Tri-Staple™ technology and predicate EEA™ Circular Stapler with DST Series™ Technology (K062850) are designed to approximate, cut and staple tissue for the purpose of creating anastomoses.

Basis for the Substantial Equivalence:

The EEA™ circular stapler with Tri-Staple™ technology has the same intended use as the identified predicate device.

They are similar in fundamental scientific technology in that they are all sterile, 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 proposed and predicate devices are similar in design, materials and are sterilized via ethylene oxide.

	Proposed Device EEA™ Circular Stapler with Tri-Staple™ Technology	**Predicate Device (K062850)** EEA™ Circular Stapler with DST Series™ Technology
Manufacturer	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 DST™ 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, including bariatric surgery.
Operation Method	Manual	Manual
Anatomical Site	Alimentary tract	Alimentary tract
Surgical Approach	Open and laparoscopic	Open and laparoscopic
Staple Rows	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 Height	3.0mm, 3.5mm, 4.0mm	3.5mm 4.8mm
Shell Diameter	28mm/31mm/33mm	21mm/25mm/28mm/31mm/33mm
Stapler Length	Standard length: 22cm Extra length XL: 35cm	Standard length: 22cm Extra length XL: 35cm
Audible Feedback	Yes	Yes
Anvil Head	3 staggered rows of anvil bucket. Lipless design	2 staggered rows of anvil bucket, Lipped design
Safety Lever	Red color	White color
Patient Contact Material(s)	Staple (implant): Titanium per ASTM F67 Grade 1 Knife: 440 Stainless Steel Anvil: 17-4 Stainless Steel Tube: Aluminum 6061 T-6	Staple (Implant): Titanium per ASTM F67 Grade 1 Knife: 440 Stainless Steel Anvil: 17-4 Stainless Steel Tube: Aluminum 6061 T-6
Biocompatibility	Yes, per ISO 10993-1	Yes, per ISO 10993-1
Single Use	Yes	Yes
Sterile	Ethylene oxide	Ethylene oxide
Shelf Life	5 years	5 years

Verification and validation activities were successfully completed. Evidence of safety and effectiveness in support of substantial equivalence were obtained from design verification and validation testing. The design differences were found to not affect safety or performance through applicable design verification activities that demonstrated conformance to applicable technical design specifications and performance requirements, applicable medical device performance standards and other nonclinical testing.

Tests performed to evaluate and compare technological and performance characteristics:

1. Stability Testing
   - *Accelerated aging test for 5 years shelf life*
2. Sterilization validation per ISO 11135-1 and ISO 10993-7
   - *Overkill method used for validation*
   - *ETO Residuals*

3. Biocompatibility testing in accordance to ISO 10993-1 and FDA guidance "*Use of International Standard ISO 10993-1*" issued June 16, 2016
    - Neutral Red Uptake (NRU) Cytotoxicity test
    - ISO Guinea Pig Maximization Sensitization
    - ISO Intracutaneous Irritation
    - ISO Acute system toxicity
    - Pyrogenicity
4. Performance Test – In Vitro
    - Staple formation
    - Anvil attach force
    - Anvil detach force
    - Firing force
5. Performance Test – In Vivo
    - External Atraumatic tissue
    - Hemostasis
    - Staple formation
    - Knife cut
    - Anastomotic burst pressure
    - Non-Clinical Chronic Study – Assessment of colo-colonic and gastro-jejunal anastomoses
6. Performance Test – Human Factors / Usability
    - Device performance evaluation per design specifications
    - Validate potential use error per Risk and Hazard analysis
    - Validate training and Instructions for Use

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion:

The performance testing including In-Vitro, In-Vivo and Human Factors/Usability were all conducted on both the subject and predicate devices. The evaluation testing concludes that the EEA™ circular stapler with Tri-Staple™ Technology was found to be substantially equivalent to the predicate device in terms of clinical performance and does not raise new questions of safety and effectiveness.

This submission does not include data from clinical studies.