August 16, 2023

Covidien
Angela Van Arsdale
Sr. Regulatory Affairs Manager
60 Middletown Ave
North Haven, Connecticut 06473

Re: K232126
Trade/Device Name: EEA™Circular Stapler with Tri-Staple™ Technology and OrVil™ Transoral Circular Stapler Anvil
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: July 17, 2023
Received: July 17, 2023

Dear Angela Van Arsdale:

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 10:36:28 -04'00'

Mark Trumbore, Ph.D.
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

IFU

Indications for Use:

The EEA™ Circular Stapler with Tri-Staple™ Technology and OrVil™ transoral circular stapler anvil 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.

510(k) Summary

Date Prepared:
July 17, 2023

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Name of Device:

Proprietary/Trade Name:	EEA™ Circular Stapler with Tri-Staple™ Technology and OrVil™ Transoral Circular Stapler Anvil
Model Numbers:	TRIEEAXL21MTORVIL, TRIEEAXL21XTORVIL, TRIEEAXL25MTORVIL, TRIEEAXL25XTORVIL
Classification Name:	Stapler, Surgical and Staple, Implantable
Regulations Number:	21 CFR 878.4740 and 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

Predicate Device:

Proprietary/Trade Name:	EEA™ Circular Stapler with Tri-Staple™ Technology
510(k) Number:	K221771, K221005
Classification Name:	Stapler, Surgical and Staple, Implantable
Regulations Number:	21 CFR 878.4740 and 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:	DST Series™ EEA™ OrVil™
510(k) Number:	K093402

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:	Staple Anvil Accessory

Device Description:
The EEA™ circular stapler with Tri-Staple™ technology and OrVil™ Transoral Circular Stapler Anvil is a manual, single-use device that places a circular, triple staggered row of titanium staples and resects the excess tissue. It 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 subject device is to add new product models with OrVil™ transoral circular stapler anvil to EEA™ circular stapler with Tri-Staple™ technology 21mm or 25mm XL purple or black stapler. Below are the descriptions of EEA™ circular stapler with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil.

OrVil™ Transoral Circular Stapler Anvil
The OrVil™ transoral circular stapler anvil comes with the anvil head secured in the tilted position. The anvil assembly is mounted on a 90 cm long PVC delivery tube and is secured to the tube with a retention suture. An advancing proximal guide suture is attached to the anvil assembly to facilitate proximal control. The advancing proximal guide suture is supplied in a reel and can be deployed as needed. When used with the EEA™ circular stapler with Tri-Staple™ technology 21mm or 25 mm XL purple or black stapler, a circular, three staggered row of titanium staples is placed. Immediately after staple formation, the stapler knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is 21 mm or 25 mm, depending on the device selected. The OrVil™ anvil is permanently affixed to the center rod and cannot be removed from the center rod. The 21mm and 25mm OrVil™ transoral circular stapler anvil is designed to be used with the corresponding 21mm or 25mm EEA™ circular stapler with Tri-Staple™ technology.

The OrVil™ Transoral Circular Stapler Anvil is essentially the same as the reference device DST Series™ EEA™ OrVil™ cleared under K093402.

EEA™ Circular Stapler with Tri-Staple™ Technology
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 determined by the selection of the 21 mm or 25mm stapler. The EEA™ circular stapler with Tri-Staple™ technology XL has a 35 cm shaft and is utilized with the OrVil™ transoral circular stapler anvil. 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 stapler is supplied without an anvil and the OrVil™ transoral circular stapler anvil packaged in a kit is utilized.

The stapler (without OrVil™ transoral circular stapler anvil part) is exactly the same as the predicate device EEA™ Circular Stapler with Tri-Staple™ Technology cleared under K221771 and K221005.

Indications for Use:
The EEA™ Circular Stapler with Tri-Staple™ Technology and OrVil™ transoral circular stapler anvil 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.

Technological Characteristics:
The subject device EEA™ Circular Stapler with Tri-Staple™ Technology and OrVil™ Transoral Circular Stapler Anvil does not change the fundamental stapling technologies employed, intended use and indications for use when compared to the predicate device EEA™ circular stapler with Tri-Staple™ technology (K221771 and K221005). The subject device is adding the OrVil™ transoral circular stapler anvil to the predicate device. The OrVil™ transoral circular stapler anvil will allow the transoral delivery of the anvil to the surgical site for the creation of anastomosis.

Substantial Equivalence:
The subject device EEA™ Circular Stapler with Tri-Staple™ Technology and OrVil™ Transoral Circular Stapler Anvil are substantially equivalent to the legally marketed EEA™ Circular Stapler with Tri-Staple™ Technology since the addition of the OrVil™ transoral circular stapler anvil, does not alter the intended use, indications, or user environment of the device.

Reference Device:
In addition to the predicate device, DST Series™ EEA™ OrVil™ (K093402) was cited in this submission. Reference device (K093402) offering OrVil™ transoral circular stapler anvil was used in comparative performance testing as a control device.

Summary of Studies:
Non-clinical performance data such as performance testing has demonstrated substantial equivalence to the predicate device.

Tests performed to evaluate and compare technological and performance characteristics:

1. Performance Test (In-Vitro)
    - Visual/Packaging Inspection
    - IFU Walkthrough
    - Firing Force on Red-Skin Foam Test
    - Staple Formation on Red-Skin Foam
    - Suture Break Test
    - Pulling Guide Suture Reel Removal
    - Proximal Guide Suture Break Test
    - Removing Guide Suture from Anvil Test
    - Removal Force with Suture Cut in 1 leg
    - Retention Break Force
    - Insertion Force of Accessory Tube Fitting
    - Retention Force of Accessory Tube Fitting

2. Performance Test (Ex-Vivo)
    - Ex-vivo Rectum Firing
    - Knife Cut Evaluation
    - Anastomotic Leak/Burst Pressure Test

3. Performance Test (In-Vivo)

- Leak Evaluation
- Staple Formation
- Hemostasis

4. Sterilization assessment per ISO 11135. Stability test for single use device.

5. Biocompatibility tests per ISO 10993-1 and Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff Document, issued on September 4, 2020.

6. Usability
Usability evaluation in accordance with the established protocol following the requirements of IEC 62366-1:2015+AMD1:2020. Usability testing is done to allow intended users (surgeons, nurses) to evaluate the subject device in simulated use and observe or inquire about any concerns for patient safety or issues with efficacy. The subject device and its instructions for use have been found to be safe and effective for the intended users, uses, and use environments.

Conclusion:
Based upon the supporting data summarized above, Covidien concludes that the subject device EEA™ Circular Stapler with Tri-Staple™ Technology and OrVil™ Transoral Circular Stapler Anvil is substantially equivalent to the legally-marketed device (K221771, K221005) and does not raise different questions of safety and effectiveness when compared with the predicate device.