September 30, 2022

Covidien
Sanja Jahr
Principal Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K221003
Trade/Device Name: Autosuture EEA Stapler (DST Serie EEA Stapler)
Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical Stapler
Regulatory Class: Class II
Product Code: GAG, GDW
Dated: August 5, 2022
Received: August 8, 2022

Dear Sanja Jahr:

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)*

Device Name
Autosuture™ EEA™ Surgical Stapler

Indications for Use *(Describe)*
The 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

Date Prepared:
August 5, 2022

Submitter:
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Subject Device:

Proprietary/Trade Name:	Autosuture™ EEA™ Stapler (DST Series™ EEA™ Stapler)
Classification Name:	Staple, Implantable and Stapler, Surgical
Regulations Number:	21 CFR 878.4750 and 21 CFR 878.4740
Product Codes:	GDW, GAG
FDA Panel Number:	79
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Stapler with implantable staple

Primary Predicate Device:

Proprietary/Trade Name:	Autosuture™ Circular EEA Surgical Stapler
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:	Stapler with implantable staple

Additional Predicate Device:

Proprietary/Trade Name:	EEA Circular Stapler with Tri-Staple Technology
510(k) Number:	K221005, K202507, K192330, K172361
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:	Stapler with implantable staple

Device Description:
The Autosuture™ EEA™ Stapler is a manual, single-use device that places a circular, double staggered row of titanium staples and resects 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.

Indications for Use:
The 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.

Technological Characteristics:
In regards to intended use, material, design, and operational principles, the subject device, Autosuture™ EEA™ Stapler, is identical to the predicate Autosuture™ EEA™ Stapler (K062850).

Non-clinical testing:
The below non-clinical testing was performed.

- Application of usability engineering to medical devices per **IEC 62366-1:2015 +AMD1:2020**
- Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging per **ASTM F2182-19**
- Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment per **ASTM F2052-21**
- Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment per **ASTM F2213-17**
- Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants per **ASTM F2119-07**
- Staple formation
- Firing force
- Staple line strength
- Staple line integrity
- In-vivo staple line hemostasis

- Biocompatibility per ISO 10993-1
- Sterilization per ISO 11135
- Stability/Shelf-life

Testing demonstrated that the subject device, Autosuture™ EEA™ Stapler, is substantially equivalent to the predicate devices, Autosuture™ Circular EEA Surgical Stapler and EEA Circular Stapler with Tri-Staple Technology (K062850 and K221005, respectively).

Clinical Testing:
This submission does not require clinical testing.

Conclusion:
Based upon the supporting data summarized above, the subject device, Autosuture™ EEA™ Stapler, is substantially equivalent to the predicate devices, Autosuture™ Circular EEA Surgical Stapler and EEA Circular Stapler with Tri-Staple Technology.