October 28, 2020

Covidien
Carolina Cabezas
Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K202864
Trade/Device Name: Tri-Staple 2.0 Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: September 23, 2020
Received: September 28, 2020

Dear Carolina Cabezas:

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,

For Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K202864

Device Name
Tri-Staple™ 2.0 Reloads

Indications for Use *(Describe)*
The Tri-Staple™ 2.0 reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures, and for transection and resection of pancreas.
The Tri-Staple™ 2.0 curved tip reloads can be used to blunt dissect or separate target tissue from other tissue.

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:
September 23, 2020

SUBMITTER:
Covidien
60 Middletown Avenue
North Haven, CT 06473 USA

CONTACT PERSON:
Carolina Cabezas Regulatory
Affairs Specialist
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IDENTIFICATION OF DEVICE:

Proprietary/Trade Name:	Tri-Staple™ 2.0 Reloads
Classification Name:	Staples, Implantable
Regulation Number:	21 CFR 878.4750
Product Code:	GDW
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Stapler with implantable non-absorbable staples

PREDICATE DEVICE:

Proprietary/Trade Name:	Signia™ Stapler
510(k) Number:	K160176 (April 26, 2016)
Classification Name:	Staples, Implantable
Regulation Number:	21 CFR 878.4750
Product Code:	GDW
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Stapler

DEVICE DESCRIPTION:
The Tri-Staple™ 2.0 Reloads and Tri-Staple™ 2.0 curved tip reloads place staggered rows of titanium staples and simultaneously divides the tissue so that three staggered rows of staples are placed on either side of the cut line. The size of the staples is determined by the selection of the single use reload:
The Tri-Staple™ 2.0 reload is available in articulating 30 mm, 45 mm and 60 mm length, the Tri-Staple™ 2.0 curved tip reload is available in articulating 30 mm, 45 mm and 60 mm lengths and the Tri-Staple™ 2.0 black reload is available in articulating 45 mm and 60 mm lengths.
The Tri-Staple™ 2.0 reloads and Tri-Staple™ 2.0 curved tip reloads can be used with the GIA™ universal stapler, Endo GIA™ universal staplers, Endo GIA™ Ultra universal staplers, and Covidien™ powered stapler handles used with Endo GIA™ adapters.

INTENDED USE/INDICATIONS FOR USE:
The Tri-Staple™ 2.0 Reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures, and for transection and resection of pancreas.
The Tri-Staple™ 2.0 curved tip reloads can be used to blunt dissect or separate target tissue from other tissue.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The purpose of this submission is a line extension to expand the reorder code offering of Tri-Staple™ 2.0 Reloads that feature the 1-Wire ID-chip assembly. Through this Special 510(k), the five new stapling reload codes will be introduced by adding the 1-wire ID Chip assembly to the Endo GIA™ Tri-Staple Reloads. The 1-wire ID-chip assembly enables communication between Tri-Staple™ 2.0 Reloads and the Signia™ Stapler, and such communication feature was cleared under the predicate K160176. The expanded product code offerings are the round tip "Core" Tri-Staple™ 2.0 Reload reorder codes.
As with current Tri-Staple™ 2.0 Intelligent Reloads and Tri-Staple™ 2.0 Intelligent curved tip reloads, the new five Tri-Staple 2.0 Reloads reorder codes place staggered rows of titanium staples and simultaneously divides the tissue so that three staggered rows of staples are placed on either side of the cut line. The size of the staple is determined by the selection of the single use reload.

Specifically, the subject "*Core"* Tri-Staple™ 2.0 Reloads when used with compatible Covidien stapler handles have the same indications for use as the "Specialty" Tri-Staple™ 2.0 Reloads previously reported under K160176. In the same manner as the "Specialty" Tri-Staple™ 2.0 Reloads previously reported under K160176, the "*Core"* Tri-Staple™ 2.0 Reloads have an encrypted 1-Wire ID-chip, thereby enabling communication between these "Core" reloads and the Signia™ Powered Handle and associated Signia™ Linear Adapters. The main difference between the subject Tri-Staple™ 2.0 Reloads and the predicate device is the subject reloads have a round tip anvil vs. the predicate reloads, which have a curved-tip anvil.

SUBSTANTIAL EQUIVALENCE:
The subject Tri-Staple™ 2.0 Reloads (new codes) are substantially equivalent to the legally marketed Tri-Staple™ 2.0 Intelligent Reloads and Tri-Staple™ 2.0 Intelligent curved tip reloads (K160176), since the addition of the 1-wire ID Chip assembly to the existing Endo GIA™ Reloads with Tri-Staple™ Technology to extend the reorder code offerings, does not alter the intended use, indications, or user environment of the device.

SUMMARY OF STUDIES:
No new non-clinical performance data or testing has been performed. The technology and design of the 1-Wire ID-chip remains the same in the subject Tri-Staple™ 2.0 Reloads. The 1-Wire ID-chip and 1-Wire communications interface for Covidien stapling reloads was previously reported in 510(k) K160176, Signia™ Stapler.
Given the fact that the design inputs and functional requirements have been previously verified, including communication with the Signia™ Stapler via the 1-wire ID-Chip assembly, the existing design verification is transferable to the subject Tri-Staple™ 2.0 Reloads (new codes). The Design Control Activities table enclosed in the submission provides the detailed rationales.

Clinical performance data – No clinical study has been performed. The substantial equivalence has been demonstrated by non-clinical studies.

CONCLUSION:
Based upon the supporting data summarized above, we concluded that this line extension to expand the reorder code offering of Tri-Staple™ 2.0 Reloads reorder codes is as safe and effective as the legally marketed Tri-Staple™ 2.0 Intelligent Reloads and Tri-Staple™ 2.0 Intelligent curved tip reloads (K160176) and does not raise different questions of safety and effectiveness than the predicate device.