July 17, 2020

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

Re: K201672
Trade/Device Name: Signia Stapler (with new software)
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: June 18, 2020
Received: June 19, 2020

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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201672

Device Name

Signia™ Stapler (with new software)

Indications for Use *(Describe)*

The Signia™ Stapler, when used with Endo GIA™ single-use reloads, Endo GIA™ single-use reloads with Tri-Staple™ Technology, Tri-Staple™ 2.0 single-use reloads and Signia™ loading units with Tri-Staple™ 2.0 single-use cartridges, has applications in abdominal, gynecological, 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 the pancreas.

The Signia™ Stapler, when used with Endo GIA™ curved tip single use reloads or Tri-Staple™ 2.0 curved tip single-use reloads, can be used to blunt dissect or separate target tissue from other certain tissue.

The Signia™ Stapler, when used with Endo GIA™ single use Radial Reloads with Tri-Staple™ Technology, has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e., low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of the pancreas.

The Signia™ Stapler, when used with Endo GIA™ single use reinforced reloads with Tri-Staple™ Technology preloaded with polyglycolic acid staple line reinforcement or Tri Staple™ 2.0 single use reinforced reloads preloaded with polyglycolic acid staple line reinforcement, has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection of tissue 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 the pancreas.

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.

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510(k) Summary of Safety and Effectiveness

DATE PREPARED:
June 18, 2020

SUBMITTER:
Covidien
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North Haven, CT 06473 USA

CONTACT PERSON:
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Principal Regulatory Affairs Specialist
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IDENTIFICATION OF DEVICE:

Proprietary/Trade Name:	Signia™ Stapler with new software
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

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 Signia™ Stapler is a battery powered microprocessor controlled surgical stapler that provides push-button powered maneuverability and firing of compatible Covidien stapling reloads. The Signia™ Stapler when used with a compatible reload is a surgical device for stapling and cutting tissues. The Signia™ Stapler is intended to be used by medical professionals qualified in the transportation, preparation, cleaning, sterilization, and use of surgical devices. All of which stay unchanged when compared to the predicate device.

The Signia™ Stapler is composed of the Signia™ Power Handle, Signia™ Power Shell, and Signia™ Linear Adapter. System accessories include the Signia™ Reusable Insertion Guide, Signia™ Manual Retraction Tool, Signia™ Single Bay Charger, Signia™ Sterilization Tray (optional), and Signia™ Four-Bay Smart Charger (optional).

The design modification is to introduce the new software version for the Signia™ Power Handle. The new software will extend the real time force gauge display on the OLED screen of the Signia™ Power Handle

for the non-intelligent reloads that are already in the market without an ID chip. Currently, the force gauge is displayed only when an intelligent reload with an ID chip is attached to the Signia™ Stapler. By installing the new software, the force gauge will be displayed consistently for all compatible Covidien reloads. This is a user interface/display change but does not impact how the handle operates.

INTENDED USE/INDICATIONS FOR USE:

The Signia™ Stapler, when used with Endo GIA™ single-use reloads, Endo GIA™ single-use reloads with Tri-Staple™ Technology, Tri-Staple™ 2.0 single-use reloads and Signia™ loading units with Tri-Staple™ 2.0 single-use cartridges, has applications in abdominal, gynecological, 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 the pancreas.

The Signia™ Stapler, when used with Endo GIA™ curved tip single use reloads or Tri-Staple™ 2.0 curved tip single-use reloads, can be used to blunt dissect or separate target tissue from other certain tissue.

The Signia™ Stapler, when used with Endo GIA™ single use Radial Reloads with Tri-Staple™ Technology, has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e., low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of the pancreas.

The Signia™ Stapler, when used with Endo GIA™ single use reinforced reloads with Tri-Staple™ Technology preloaded with polyglycolic acid staple line reinforcement or Tri-Staple™ 2.0 single use reinforced reloads preloaded with polyglycolic acid staple line reinforcement, has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection of tissue 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 the pancreas.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Signia™ Stapler with new software does not change the fundamental operating principle and mechanism of action when compared to the predicate device. The Signia™ Stapler remains as a powered surgical stapler operated by the built-in battery and microprocessor with software. The user controls the Signia™ Stapler via button presses on the Handle and receives feedback status and other information via its LED indicators, OLED display, and audible tones. Push buttons on the handle are provided for stapling activation (firing/clamping/unclamping), articulation (left/right), and rotation (clockwise/counterclockwise).

The Signia™ Stapler includes adaptive stapling algorithm (ASA) in its software, which is often referred as adaptive firing technology or tissue sensing technology. This feature measures force when clamping and firing staples during use and will prevent the force from exceeding predetermined safety limits. As it enters three specially developed, predetermined force zones, the Signia handle will adjust its firing speed in order to maintain forces within the lowest zone possible and optimize staple formation. Based on the initial force measured during clamping, the device will program the initial appropriate speed selection. There are three speed settings set from clamp force: Zone 1 Standard, Zone 2 Medium, and Zone 3 Slow.

SUBSTANTIAL EQUIVALENCE:

The Signia™ Stapler with the new software is substantially equivalent to the legally marketed Signia™ Stapler (K160176) since extending the existing real time force gauge display to cover all Covidien reloads through software change does not alter the intended use, indications, or user environments of the device. Applicable design control activities to ensure the Signia™ Stapler with new software functions as

intended have been completed without raising different types of questions in terms of safety and effectiveness when compared to the predicate device.

SUMMARY OF STUDIES:
Non-clinical performance data such as software verification & validation and performance testing have demonstrated substantial equivalence to the predicate device.

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 Signia™ Stapler with the new software is as safe and effective as the legally marketed K160176 and does not raise different questions of safety and effectiveness than the predicate device.