March 14, 2019

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

Re: K182475

Trade/Device Name: Signia Circular Adapters (for use with Signia Staplers), Tri-Staple 2.0 Circular Reloads (for use with Signia Circular Adapters)

Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: September 7, 2018
Received: September 10, 2018

Dear Ms. 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
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 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

Digitally signed by David Krause -S
Date: 2019.03.14 08:09:44 -04'00'

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
Indications for Use

510(k) Number (if known)
K182475

Device Name
Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads (For use with Signia™ Stapler)

Indications for Use (Describe)
The Signia™ stapler, when used with the Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads, has applications 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.

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510(k) Summary

DATE PREPARED:
March 13, 2019

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

CONTACT PERSON:
Katherine Y. Choi, RAC
Principal Regulatory Affairs Specialist
Telephone: (203) 492-8412
Fax: (203) 492-5029

IDENTIFICATION OF DEVICE:
Proprietary/Trade Name: Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads
(For use with Signia™ Stapler)
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: EEA™ circular stapler with Tri-Staple™ technology
510(k) Number: K172361 (Feb 16, 2018)
Classification Name: Staples, Implantable
Regulation Number: 21 CFR 878.4750
Product Code: GDW, GAG
Device Class: Class II
Review Panel: General and Plastic Surgery
Common Name: Surgical Stapler

DEVICE DESCRIPTION:
The Signia™ stapler, when used with the Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads, is a battery powered microprocessor controlled surgical stapler that provides push-button powered maneuverability and firing of compatible reloads. The Signia™ Stapler is intended to be used by medical professionals qualified in the transportation, preparation, cleaning, sterilization, and use of surgical devices. The Signia™ stapler is intended for use in a sterile operating room environment in surgical procedures where surgical stapling is indicated.

The Signia™ Stapler has been previously cleared through K160176 for use with various Covidien reloads. By introducing new devices such as Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads, the Signia™ Stapler can be used for the new indication of creating circular anastomoses throughout the alimentary tract in both open and laparoscopic surgeries.
The Signia™ circular adapters are reusable instruments that connect with the assembled Signia™ Power Handle and the Signia™ Power Shell to make up the Signia™ stapler. The circular adapters are composed of motor-mating connectors, sensor gauge, and device communications interfaces to provide functionality and communications between compatible reloads and the Signia™ Power Handle. The user can manually rotate the handle in 0, 90, 180 degrees to position the device if required, and the user can fire within these locked and rotated positions. The circular adapters are available in two shaft lengths, standard and extra-long, and both sizes are compatible with the new Tri-Staple™ 2.0 circular reloads.

The Tri-Staple™ 2.0 circular reloads place a circular triple staggered row of titanium staples. After staple formation, the knife blade resects the excess tissue, creating a circular anastomosis such as end-to-end, end-to-side, or side-to-side anastomosis as the user sees fit. The new circular reloads will be offered for a medium/thick tissue thickness range, which is identified by the purple staple guide. The circular reloads deploy three height-progressive rows of 3.0 mm, 3.5 mm and 4.0 mm titanium staples. The Tri-Staple™ 2.0 technology incorporated in the reloads is essentially the same as the legally-marketed predicate K172361 in terms of reload design. The circular reloads are provided sterile for single use, and available in five lumen sizes: 21, 25, 28, 31, and 33 mm. The Tilt-Top™ anvil is available with all circular reloads.

To create a circular anastomosis, the Signia™ Stapler consists of the Signia™ Power Handle, Signia™ Power Shell, Signia™ Circular Adapter, and Tri-Staple™ 2.0 circular reload. The existing system accessories such as Signia™ Reusable Insertion Guide, Signia™ Manual Retraction Tool, Signia™ Single Bay Charger, Signia™ Sterilization Tray (optional), and Signia™ Four-Bay Smart Charger (optional) can be also used.

INTENDED USE/INDICATIONS FOR USE:
The Signia™ stapler, when used with the Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads, has applications 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.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:
The Tri-Staple™ technology used in the subject devices are fundamentally the same as the predicate device K172361 with an exception that the subject devices employ the powered stapling technology. Covidien is extending the powered feature to the circular stapling application as an evolution of stapling technology to utilize the advantages of powered stapling, such as push-button operations, and controlled compression, stapling, and cutting, which resulted in consistent staple lines when compared to the manual instrument where the same actions are achieved through the user’s manual force. This is accomplished by introducing the new devices for the currently-marketed Signia™ Stapler (K160176).

SUBSTANTIAL EQUIVALENCE:
The Signia™ stapler, when used with the Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads, is the same as the legally-marketed EEA™ Circular Stapler with Tri-Staple™ Technology in K172361 in terms of the intended use and indications for use. Covidien’s proprietary Tri-Staple™ technology is fundamentally the same between the subject and predicate devices. The notable difference is the operating principle of powered versus manual. For example, the clamp, staple, and cut strokes are controlled separately in the Signia™ stapler whereas the predicate device performs the staple and cut functions almost simultaneously. Also, the subject devices are equipped with an advanced software algorithm called Controlled Tissue Compression (CTC). The subject devices offer several safety features controlled by software as well as a manual recovery process using the retraction tool. The below table further summarizes the similarities and differences between the subject and predicate devices.
<table>
<thead>
<tr>
<th>Feature</th>
<th>New/Subject Devices</th>
<th>Predicate Device K172361</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td>The Signia™ stapler, when used with the Signia™ circular adapters and Tri Staple™ 2.0 circular single use reloads, has applications 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.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Operating Principle</strong></td>
<td>Software-controlled and powered by a built-in battery with push button controls, and Controlled Tissue Compression (CTC) feature</td>
<td>Manual - activated by squeezing the handle firmly as far as it will go.</td>
</tr>
<tr>
<td><strong>Construction</strong></td>
<td>Signia™ Stapler consists of the Signia™ Power Handle, Signia™ Power Shell, Signia™ Circular Adapter (Standard and XL), and Tri-Staple™ 2.0 circular single-use reload</td>
<td>One integrated piece with handle and reload, unable to detach</td>
</tr>
<tr>
<td><strong>Stapler Shaft Length</strong></td>
<td>Circular Adapter Standard: 25cm Circular Adapter XL: 30cm</td>
<td>Standard length: 22cm Extra length XL: 35cm</td>
</tr>
<tr>
<td><strong>Audible Feedback</strong></td>
<td>Electronic beeps</td>
<td>Manual clicks</td>
</tr>
<tr>
<td><strong>Firing Force</strong></td>
<td>Pushing the toggle key to fire</td>
<td>Manual squeezing to fire (staple and cut)</td>
</tr>
<tr>
<td><strong>Safety Features</strong></td>
<td>Various error handlings and recovery modes</td>
<td>Manual Safety Lever</td>
</tr>
<tr>
<td><strong>Intelligent Interface</strong></td>
<td>Yes - Provided intelligent interface of reloads and adapters with ID-chips</td>
<td>No electronic parts</td>
</tr>
<tr>
<td><strong>Reusable Device</strong></td>
<td>Signia™ Circular Adapters (including trocar) and Trocar Tip protector are reusable</td>
<td>The entire device is for single use</td>
</tr>
<tr>
<td><strong>Biocompatibility</strong></td>
<td>Evaluated per ISO 10993 series and FDA 2016 biocompatibility guidance</td>
<td>Evaluated per ISO 10993 series and FDA 2016 biocompatibility guidance</td>
</tr>
<tr>
<td><strong>Tri-Staple™ 2.0 Circular Reloads</strong></td>
<td></td>
<td>Tri-Staple™ Technology: 3 staggered rows of staples with different staple height in each staple row</td>
</tr>
<tr>
<td><strong>Staple Design</strong></td>
<td>Same as the predicate</td>
<td>Same as the predicate</td>
</tr>
<tr>
<td><strong>Staple Height</strong></td>
<td>Same as the predicate 3.0mm, 3.5mm, 4.0mm</td>
<td>3 staggered rows of anvil bucket, Lipless design.</td>
</tr>
<tr>
<td><strong>Anvil Design</strong></td>
<td>Same as the predicate</td>
<td>Over mold center rod design</td>
</tr>
<tr>
<td><strong>Anvil Center Rod</strong></td>
<td>Same as the predicate</td>
<td></td>
</tr>
<tr>
<td><strong>Indicated Tissue Thickness Range</strong></td>
<td></td>
<td>Medium/Thick (purple) reloads: 1.5 - 2.25 mm (0.060” - 0.090”)</td>
</tr>
<tr>
<td><strong>Lumen Sizes</strong></td>
<td>21mm/25mm/28mm/31mm/33mm</td>
<td>28mm/31mm/33mm</td>
</tr>
<tr>
<td><strong>Sterilization Method</strong></td>
<td>Same as the predicate</td>
<td>Ethylene oxide (EO)</td>
</tr>
<tr>
<td><strong>Other Devices Packaged with the Reloads</strong></td>
<td></td>
<td>Tilt-Top™ anvil</td>
</tr>
<tr>
<td></td>
<td>• Tilt-Top™ anvil</td>
<td>Anvil tips (blunt or sharp)</td>
</tr>
<tr>
<td></td>
<td>• Anvil tips (blunt or sharp)</td>
<td>Tri-Staple™ 2.0 introducer device (also known as TAIDs) for 21 and 25 mm</td>
</tr>
<tr>
<td></td>
<td>• Irrigation channel (optional accessory)</td>
<td>Tilt-Top™ anvil</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anvil tips (blunt or sharp)</td>
</tr>
</tbody>
</table>
SUMMARY OF STUDIES:
Non-clinical performance data – The following testing has been performed to demonstrate substantial equivalence to the predicate device. When possible, applicable FDA-recognized standards were considered:

- Stability/Shelf life study results support a 5-year shelf life of the single use devices.
- Ethylene oxide (EO) sterilization validation demonstrates the sterilization cycle used for the single use devices can effectively achieve a minimum Sterility Assurance Level (SAL) of $10^{-6}$.
- Reprocessing validation performed per the FDA 2015 reprocessing guidance demonstrates that, when the reprocessing instructions are followed, the new reusable devices can be properly cleaned and sterilized prior to each use.
- Reliability data supports the end of life of the reusable adapters.
- Biocompatibility evaluation conducted in accordance with the FDA’s 2016 guidance and ISO 10993-1 supports that the subject devices are biocompatible.
- Software verification & validation activities completed in accordance with the FDA’s 2015 guidance and IEC 62304 demonstrates that, when the subject devices are used with the Signia™ Stapler, they successfully meet the software specifications.
- Electrical safety testing per ANSI/AAMI ES 60601-1 & IEC 60601-1 and electromagnetic compatibility (EMC) testing per IEC 60601-1-2 confirms that the new devices meet safety requirements.
- Performance testing such as bench top, in-vivo and ex-vivo animal testing demonstrates the substantial equivalence of the subject devices as compared to the predicate device and/or meeting the product specifications. Such testing includes, for example, chip communication test, interlock test, linear to EEA back to linear firings, tissue abrasion, hemostasis, staple formation in media and animal tissue, burst test, and across staple line firing.
- Usability evaluation performed following IEC 60601-1-6 and IEC 62366-1 demonstrates that the subject devices meet product design specifications by verifying various use cases as well as Instructions for Use (IFU) and training.
- Chronic animal study performed to evaluate the performance of the subject device and predicate device shows no differences in healing metrics or anastomotic index, and the results demonstrate that the acceptance criteria were met.

Clinical performance data – No clinical study is deemed necessary since the substantial equivalence has been sufficiently demonstrated by non-clinical studies.

CONCLUSION:
Based upon the supporting data summarized above, we concluded that the new devices Signia™ circular adapters and Tri-Staple™ 2.0 circular single use reloads are, when used with the already-marketed Signia™ stapler, as safe and effective as the legally-marketed predicate device K172361, and does not raise different questions of safety and effectiveness than the predicate device.