DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 2, 2017

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

Re: K170348
Trade/Device Name: Signia Four-Bay Smart Charger (to Be Used With Signia Stapler)
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: February 2, 2017
Received: February 3, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170348

Device Name

Signia™ Four-Bay Smart Charger

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.

510(k) Summary of Safety and Effectiveness

DATE PREPARED:
February 2, 2017

SUBMITTER:
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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™ Four-Bay Smart Charger (to be used 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:	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 is compatible 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. The Signia™ Stapler when used with the abovementioned family of Endo GIA™ reloads 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, and this submission introduces a new accessory, Signia™ Four-Bay Smart Charger. The Smart Charger's primary purpose remains the same as the Signia™ Single-Bay Charger in K160176, but the difference is that Smart

Charger offers enhanced features such as four charging stations, a touch-screen LCD display, and data management interface in order to improve user convenience.

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™ Four-Bay Smart Charger is designed for use as an accessory with the Signia™ stapler, which includes four power handle charging bays and a touch-screen LCD display screen. Its purpose is to charge the Signia™ power handle. The touchscreen LCD is used to indicate the power handle's charge status. Like the marketed Signia™ Single Bay Charger in K160176, the Signia™ Four-Bay Smart Charger employs the smart charging mechanism that provides necessary voltage and current regulation for the given battery chemistry.

SUBSTANTIAL EQUIVALENCE:

The Signia™ Stapler used with the Signia™ Four-Bay Smart Charger is substantially equivalent to the legally-marketed Signia™ Stapler used with the Signia™ Single-Bay Charger (K160176) since adding a new charger does not affect the stapling technologies employed. Also, when compared to the Signia™ Single-Bay Charger, the key difference is the Smart Charger offers enhanced features such as four charging stations, touch-screen LCD display and data ports. Other product specifications are very similar.

SUMMARY OF STUDIES:

Non-clinical performance data – Tests performed to demonstrate continued conformance with the FDA recognized standards includes:

1. Software Verification & Validation per IEC 62304
2. Electrical Safety Testing per ANSI/AAMI ES 60601-1 & IEC 60601-1
3. EMC Testing per IEC 60601-1-2
4. Usability Evaluation per IEC 60601-1-6 & IEC 62366-1

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 accessory, Signia™ Four-Bay Smart Charger is as safe and effective as the legally marketed device K160176, and does not raise different questions of safety and effectiveness than the predicate device.