JAN - 8 2014

510(k) Summary

SUBMITTER:	Covidien llc 60 Middletown Avenue North Haven, CT 06473 USA
CONTACT PERSON:	Debra Peacock Regulatory Affairs Product Manager Covidien llc Phone: (203) 492-6935 Fax: (203) 492-5029 e-mail: debra.peacock@covidien.com
DATE PREPARED:	12/09/13
PRODUCT CODE:	GDW
REGULATION NUMBER:	21 CFR 878.4750
TRADE/PROPRIETARY NAME:	Endo GIA™ Extra Long Adapter
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staples
CLASSIFICATION NAME:	Staple, Implantable
PREDICATE DEVICES:	iDrive™ Ultra and Endo GIA™ Adapter (K121510)
DEVICE DESCRIPTION:	The Endo GIA™ Extra Long Adapter (EGIAADAPTXL) is a longer version of our currently cleared Endo GIA™ Standard Adapter (EGIAADAPT). The Endo GIA™ adapter converts the rotary output of the iDrive™ Ultra powered handle to linear motion, enabling compatibility with all Endo GIA™ stapling reloads units. The iDrive™ Ultra powered handle and Endo GIA™ adapter are multi-patient reusable devices. The devices will deactivate after reaching the end of their service life. The devices are to be used by medical professionals qualified in the transportation, preparation, cleaning, sterilization, and use

of surgical devices. Endo GIA™ single use loading units and reloads with Tri-Staple™ Technology are intended for use in a sterile operating room environment in surgical procedures where surgical stapling is indicated.

The Endo GIA™ Extra Long Adapter is being introduced to enable medical professionals with a choice of adapters for ease of access.

INTENDED USE

The iDrive™ Ultra powered handle and Endo GIA™ adapter, when used with Endo GIA™ single use reloads have 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 pancreas.

The iDrive™ Ultra powered handle and Endo GIA™ adapter, when used with Endo GIA™ curved tip single use reloads, can be used to blunt dissect or separate target tissue from other certain tissue.

The iDrive™ Ultra powered handle and Endo GIA™ adapter, when used with the Endo GIA™ Radial Reload 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 pancreas.

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TECHNOLOGICAL CHARACTERISTICS:

Characteristic	Proposed Endo GIA™ Extra Long Adapter	Predicate iDrive™ Ultra and Endo GIA™ Adapter (K121510/ K123318)
IFU	Same	Same
System Component	Same	Endo GIA™ adapter indicated for use with the iDrive™ Ultra Powered Stapling System.
Materials	Same (No change in materials from previous device).	All patient-contacting components of the iDrive™ Ultra powered handle and Endo GIA™ adapter are comprised of materials that have been evaluated in accordance with ISO 10993-1: 2009, Biological Evaluation of medical devices – Part 1: Evaluation and Testing.
Adapter Dimensional Specifications	14.07" (total length) 1.52" (max width)	10.27" (total length) 1.25" (max width)
Configuration	Same	Endo GIA™ adapter and Endo GIA™ reloads delivers two sets of triple staggered rows of titanium staples and simultaneously divides the tissue between the two rows of staples via the single use reload, initiated by buttons on the powered handle
Labeling	Unchanged (universal adapter IFU)	Same

MATERIALS: There are no changes in materials for the Endo GIA™ Extra Long Adapter (EGIAADAPTXL) from the predicate Endo GIA™ adapter. All materials are in accordance with ISO 10993-1.

PERFORMANCE DATA: Design verification studies were conducted to demonstrate that the proposed device, the Endo GIA™ Extra Long Adapter substantially equivalent to the predicate device.

In-vitro testing supports the intended use of this device includes:

In-vitro Testing:
- Articulation and rotation verification
- Staple formation verification
- Knife cutting performance verification
- Lifecycle reliability test

Electrical safety testing
Biocompatibility testing

CONCLUSION:

The results of testing demonstrate that the modified Endo GIA™ Extra Long Adapter is substantially equivalent to the legally marketed Endo GIA™ Adapter (K121510).

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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

Covidien
Ms. Debra Peacock
Regulatory Affairs Product Manager
60 Middletown Avenue
North Haven, Connecticut 06473

January 8, 2014

Re: K133762
Trade/Device Name: Endo GIA™ Extra Long Adapter
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: December 9, 2013
Received: December 11, 2013

Dear Ms. Peacock:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133762_

Device Name
Endo GIA™ Extra Long Adapter

Indications for Use *(Describe)*

The iDrive™ Ultra powered handle and Endo GIA™ adapter, when used with Endo GIA™ single use reloads have 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 pancreas.

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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S