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510(k) Summary of Safety and Effectiveness

JUL 25 2012

SUBMITTER:	Covidien llc (formerly registered as Tyco Healthcare, LP) 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-5000
CONTACT PERSON:	Sarah Rizk Senior Product Specialist, Regulatory Affairs Covidien llc Phone: (203) 492-5493 Fax: (203) 492- 5029
DATE PREPARED:	May 18, 2011
TRADE/PROPRIETARY NAME:	iDrive™ Ultra powered handle Endo GIA™ adapter iDrive™ Battery Insertion Guide
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staples
CLASSIFICATION NAME:	Staple, Implantable
PREDICATE DEVICE(S):	Covidien, iDrive™ system (K102325) Covidien, Endo GIA™ Ultra Universal Stapler (K111825)
DEVICE DESCRIPTION:	Surgical stapler with a powered handle, delivering implantable titanium staples.
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:	The iDrive™ Ultra powered handle with the 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.
MATERIALS:	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.
PERFORMANCE DATA:	In-vitro and in-vivo testing to support the intended use of this device includes: o Articulation and Rotation Verification o Staple Formation Verification o Visual Indication Intensity o Aseptic Battery Transfer Test o Grasping Capability o Tissue Trauma Evaluation o Knife Cutting Performance Verification o Lifecycle Reliability Test Additional bench top testing has been performed and includes testing to the following electrical safety standards: o IEC 60601-1: 1988 + A1 (1991) + A2 (1995) o IEC 60601-1-2: 2007 o IEC 60601-2-18: 1996+ A1 (2000)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

COVIDIEN, FORMERLY US SURGICAL A DIVISION OF TYCO
% Ms. Sarah Rizk
Regulatory Affairs Product Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

JUL 25 2012

Re: K121510
Trade/Device Name: iDrive Ultra Powered Handle and Endo GIA adapter
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: May 18, 2012
Received: May 21, 2012

Dear Ms. Rizk:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Enid Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: iDrive ™ Ultra powered handle and Endo GIA ™ adapter

Indications For Use:

The iDrive ™ Ultra powered handle and En do GIA ™ adapter, when used with En do 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 TM adapter, when used with Endo GIA TM 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 En do GIA TM adapter, when used with the Endo GIA TM 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.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121510