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510(k) Summary of Safety and Effectiveness

SUBMITTER:	Covidien llc (formerly registered as Tyco Healthcare, LP) 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-5000
CONTACT PERSON:	Nishith Desai Associate Manager, Regulatory Affairs Covidien llc Phone: (203) 492-6339 Fax: (203) 492- 5029
DATE PREPARED:	August 16, 2010
TRADE/PROPRIETARY NAME:	iDrive™ System
COMMON/USUAL NAME:	Implantable, Staple
CLASSIFICATION NAME:	Surgical devices – Staple, Implantable
PREDICATE DEVICE(S):	Covidien, iDriveC (K073001) Covidien, RALC (K012809) Ethicon, CONTOUR Curved Cutter Stapler (K091322) Covidien, Autosuture TA DST Series Stapler (K013860, K801589)
DEVICE DESCRIPTION:	Surgical stapler with Powered Handle, delivering implantable titanium staples.
INTENDED USE:	iDrive™ Powered Handle The Covidien iDrive™ Powered Handle, when used with the Covidien™ iDrive™ Right Angle Linear Cutter (RALC) Single Use Reload, is intended for use in gastrointestinal, gynecological, and general abdominal and thoracic surgery for resection, transection of tissues, and creation of anastomoses. iDrive™ RALC The Covidien iDrive™ Right Angle Linear Cutter (RALC) Single Use Reload, when used with the Covidien™ iDrive™ Powered Handle, is intended for use in gastrointestinal, gynecological, and general abdominal and thoracic surgery for resection, transection of tissues, and creation of anastomoses.
TECHNOLOGICAL CHARACTERISTICS:	The iDrive™ Powered Handle with the iDrive™ Right Angle Linear Cutter delivers 2 rows of surgical staples on each side of the cutting blade, initiated by buttons on the powered handle.
MATERIALS:	All patient-contacting components of the iDrive™ Powered Handle and iDrive™ Right Angle Linear Cutter are comprised of materials that have been evaluated in accordance with ISO

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10993-1: 2003, 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:

- Staple line pull-apart strength test
- Staple formation test
- Staple line burst strength test
- Hemostasis (free bleed time) evaluation
- Air leak test
- Tissue trauma evaluation
- Knife Cutting Performance test
- Product security on Tissue test while clamping and firing
- Autoclave Reliability test
- Egress of material test
- Fire and clamp Shaft peak stall output torque measurement
- Battery and Battery charger tests

Additional bench top testing has been performed and includes testing to the following electrical safety standards:

- IEC 60601-1: 1988 + A1 (1991) + A2 (1995)
- IEC 60601-1-2: 2007
- IEC 60601-1-8: 2006

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, LLC
% Nishith Desai
Associate Manager, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K102325
Trade/Device Name: iDrive™ System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: August 16, 2010
Received: August 17, 2010

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Dear Nishith Desai:

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,

For

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

Enclosure

Indications for Use

510(k) Number (if known): K102325

Device Name: : iDrive™ System

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Indications For Use

iDrive™ Powered Handle
The iDrive™ Powered Handle, when used with the iDrive™ Right Angle Linear Cutter (RALC) Single Use Reload, is intended for use in gastrointestinal, gynecological, and general abdominal and thoracic surgery for resection, transection of tissues, and creation of anastomoses.

iDrive™ RALC
The iDrive™ Right Angle Linear Cutter (RALC) Single Use Reload, when used with the iDrive™ Powered Handle, is intended for use in gastrointestinal, gynecological, and general abdominal and thoracic surgery for resection, transection of tissues, and creation of anastomoses.

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)

David Krause for MKM

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

510(k) Number K102325