

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



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.

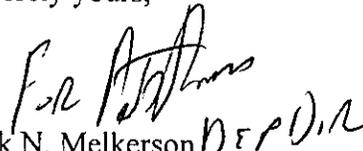
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,

  
Mark N. Melkerson  
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   
(Part 21 CFR 801 Subpart D)

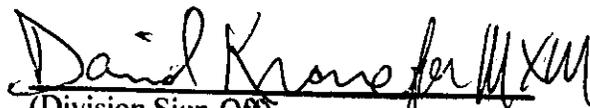
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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