5. 510(k) SUMMARY:

K093402

510(K) Summary of Safety and Effectiveness:

SUBMITTER:	Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien) 60 Middletown Avenue North Haven, CT 06473
CONTACT PERSON:	Rebecca Ronner Associate, Regulatory Affairs Phone: (203) 492-5438 Fax: (203) 492-5029
DATE PREPARED:	October 30, 2009
TRADE/PROPRIETARY NAME:	Autosuture™ EEA™ Orvil™
COMMON/USUAL NAME:	Stapler Anvil Accessory
CLASSIFICATION NAME:	Implantable Staple
PREDICATE DEVICE(S): (Note: There are no modifications to the previously cleared devices.)	K024275: Autosuture™ Premium Plus CEEA™ Disposable Stapler K062850: Autosuture™ EEA Surgical Stapler™
DEVICE DESCRIPTION:	The DST Series™ EEA™ 21, 25 or 28 mm stapler, creates a circular, double staggered row of titanium staples. Immediately after staple formation, the stapler knife blade resects the excess tissue, creating a circular anastomosis. The DST Series™ EEA Surgical Stapler comes with a detachable anvil. As an accessory to this instrument we have modified the detachable anvil assembly to create the DST Series OrVil™. The anvil assembly is mounted on a delivery tube and is secured to the tube. A retraction suture is also tied to the anvil assembly.
INTENDED USE:	The DST Series™ EEA™ OrVil™ 21 mm device when used with the appropriate DST Series™ EEA™ stapler has applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries, including bariatric surgery.
TECHNOLOGICAL CHARACTERISTICS:	DST Series™ EEA™ OrVil™ Device is equivalent to the predicate devices in terms of its intended use. DST Series™ EEA™ OrVil™ modified the design of the predicate device to include a retraction suture. The suture will allow the anvil to be manipulated in the event it gets lodged in transit. The predicate design was also modified to include 28mm size device.

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MATERIALS: CHARACTERISTICS:	DST Series™ EEA™ OrVil™ Devices is comprised of materials which have been evaluated in accordance with ISO 10993-1: 2003, Biological Evaluation of medical devices – Part I Evaluation and Testing and is identical to the predicate device.
PERFORMANCE DATA:	In-vitro and in-vivo tests were performed to verify that the performance of the DST Series™ EEA™ OrVil™ Device is substantially equivalent to the predicate devices, and to validate the at DST Series™ EEA™ OrVil™ Device will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Surgical Devices
Tyco Healthcare Group LP
(d/b/a Covidien)
% Ms. Rebecca Ronner
Associate, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K093402
Trade/Device Name: DST Series™ EEA™ OrVil™
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 30, 2009
Received: November 2, 2009

Dear Ms. Ronner:

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.

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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

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): K093402

Device Name: DST Series ™ EEA™ OrVil™

The DST Series ™ EEA™ OrVil™ 21 mm device when used with the DST Series™ EEA™ 21 mm stapler, the DST Series ™ EEA™ OrVil™ 25 mm device when used with the DST Series™ EEA™ 25mm stapler, and the DST Series ™ EEA™ OrVil™ 28 mm device when used with the DST Series™EEA™ 28 mm stapler has applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries, including bariatric surgery.

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 K093402