K062850 page 1/1

510(k) Summary of Safety and Effectiveness

SUBMITTER:	United States Surgical, a division of Tyco Healthcare Group LP 150 Glover Avenue Norwalk, CT 06856 Tel. No.: (203) 845-1000
CONTACT PERSON:	Frank Gianelli Senior Associate, Regulatory Affairs
DATE PREPARED:	September 21, 2006
TRADE/PROPRIETARY NAME:	autosuture™ Circular EEA™ surgical staplers
COMMON/USUAL NAME:	Implantable Staple
CLASSIFICATION NAME:	Implantable Staple
PREDICATE DEVICE(S):	autosuture™ Premium Plus CEEA™ Disposable Stapler (K024275)
DEVICE DESCRIPTION:	The autosuture™ Circular EEA™ family of staplers place a circular, double staggered row of titanium staples and resects the excess tissue, creating a circular anastomosis. They are indicated for use in the creation of anastomoses in various surgical procedures in both open and laparoscopic surgeries.
INTENDED USE:	The autosuture™ Circular EEA™ Staplers have application 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:	The autosuture™ EEA™ stapler is identical to the predicate device in terms of intended use and it operates in a similar manner as the predicate device. The only difference is a modification of the wire gauge diameter of the titanium staple.
MATERIALS:	All components of the autosuture™ EEA™ stapler are comprised of materials which are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	In-vitro and in-vivo tests were performed to verify that the modified autosuture™ EEA™ stapler is substantially equivalent to the predicate device for use in the creation of anastomoses in various surgical procedures in both open and laparoscopic surgeries.

OCT 23 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

United States Surgical
a division of Tyco Healthcare Group, LP
% Mr. Frank Gianelli
Senior Associate, Regulatory Affairs
195 McDermott Road
North Haven, Connecticut 06473

OCT 2 3 2006

Re: K062850
Trade/Device Name: **autosuture™ EEA™ Surgical Stapler**
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: September 22, 2006
Received: September 26, 2006

Dear Mr. Gianelli:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications For Use

510(k) Number (if known): K062850

Device Name: **autosuture™ EEA™ Surgical Stapler**

Indications For Use:

The autosuture™ Circular EEA™ Staplers have application 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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 General, Restorative, and Neurological Devices

510(k) Number K062850