DEC - 1 2003

K032696

IX. 510(k) Summary of Safety and Effectiveness

SUBMITTER:	United States Surgical 150 Glover Avenue Norwalk, CT 06856
CONTACT PERSON:	Chester McCoy
DATE PREPARED:	November 14, 2003
CLASSIFICATION NAME:	Staple, Implantable
COMMON NAME:	Staple, Implantable
PROPRIETARY NAME:	Auto Suture* TA* & GIA* Staplers
PREDICATE DEVICES:	Auto Suture* TA* & GIA* Staplers
TECHNOLOGICAL CHARACTERISTICS:	The Auto Suture* TA* & GIA* Staplers are identical to the predicate devices. The only changes are in the indication for use statement.
DEVICE DESCRIPTION:	The Auto Suture* TA* & GIA* Staplers are designed to place multiple staggered rows of titanium or stainless steel staples in various types of tissues.
INTENDED USE:	The Auto Suture* TA* & knifeless GIA* staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses, including occlusion of the left atrial appendage in open procedures.
MATERIALS:	All component materials of the Auto Suture TA* & GIA* staplers are comprised of materials which are in accordance with ISO Standard #10993-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2003

Mr. Chester McCoy
Director of Regulatory Affairs
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K032696
Trade/Device Name: Auto Suture TA Surgical Staplers
Auto Suture Knifeless GIA Surgical Staplers
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: August 29, 2003
Received: September 2, 2003

Dear Mr. McCoy:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K032696

IV. Indications For Use:

510(k) Number (if known): K032696

Name: Auto Suture* TA* Surgical Staplers
Auto Suture* Knifeless GIA* Surgical Staplers

Indications For Use:

The Auto Suture* TA* & knifeless GIA* staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses, including occlusion of the left atrial appendage in open procedures.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use:
(Per 21 CFR §801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032696