K013860

IX. Summary of Safety and Effectiveness

DEC 1 9 2001

SUBMITTER:	United States Surgical A division of Tyco Healthcare Group, LP 150 Glover Avenue Norwalk, CT 06856
CONTACT PERSON:	Chester McCoy
DATE PREPARED:	November 20, 2001
CLASSIFICATION NAME:	Implantable Staple
COMMON NAME:	Implantable Staple, General and Plastic Surgery
PROPRIETARY NAME:	Auto Suture* Surgical Staples
PREDICATE DEVICES:	Auto Suture* Modified Surgical Staples (K855047).
INTENDED USE:	The Auto Suture Surgical Staples are intended to be used with the currently marketed Auto Suture TA Stapler and Single Use Loading Unit (SULU), Auto Suture GIA Stapler and SULU, and Auto Suture EEA Stapler and SULU.
MATERIALS:	Titanium – The staples are comprised of a material which is in compliance to ISO Standard #10993-1
PERFORMANCE DATA:	In vitro and in vivo testing was performed to verify that the Auto Suture* Surgical Staples can be used with the Auto Suture TA Stapler and Single Use Loading Unit (SULU), Auto Suture GIA Stapler and SULU, and Auto Suture EEA Stapler and SULU.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2001

Chester McCoy
Program Manager
Regulatory Affairs
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K013860
Trade Name: Auto Suture Surgical Staples
Regulation Number: 878.4750
Regulation Name: Implantable Staple
Regulatory Class: II
Product Code: GDW
Dated: November 20, 2001
Received: November 21, 2001

Dear Mr. McCoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Neil R.P. Ogden 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

V. Indications for Use

510(k) Number (if known): K013860

Device Name: Auto Suture Surgical Staples

Indications For Use:

The Auto Suture Surgical Staples are intended to be used with the currently marketed Auto Suture TA Stapler and Single Use Loading Unit (SULU), Auto Suture GIA Stapler and SULU, and Auto Suture EEA Stapler and SULU.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

MRO for CMW

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013860