2/10/99

K983400

IX. 510(k) Summary of Safety and Effectiveness

SUBMITTER:	United States Surgical Corporation 150 Glover Avenue Norwalk, CT 06856
CONTACT PERSON:	Christopher A. Graham
DATE PREPARED:	September 22, 1998
CLASSIFICATION NAME:	Implantable Staple
COMMON NAME:	Implantable Staple
PROPRIETARY NAME:	Auto Suture* Site Marker** staple
PREDICATE DEVICES:	MicroMark™ clip (K970817)
DEVICE DESCRIPTION:	The Auto Suture* Site Marker** staple, is a single use disposable staple, which consists of a non-absorbable material that is clearly visible on a radiograph. The staple is deployed into soft tissue during open or percutaneous procedures to mark a surgical location for radiograph by a manual stapler.
INTENDED USE:	The Auto Suture* Site Marker** staple is intended for use in soft tissue during an open or percutaneous biopsy procedure to radiographically mark the location.
MATERIALS:	All component materials of the Auto Suture* Site Marker** staple 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

FEB 10 1999

Christopher A. Graham
Associate, Regulatory Affairs
United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856

Re: K983400
Auto Suture Site Marker Staple
Dated: January 6, 1999
Received: January 7, 1999
Regulatory class: II
21 CFR 878.4750/Procode: 90 GDW

Dear Mr. Graham:

We have reviewed your Section 510(k) 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 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications For Use:

510(k) Number (if known): _____

Name: Auto Suture* Site Marker**

Indications For Use:
The Auto Suture* Site Marker** staple is intended for use in soft tissue during an open or percutaneous biopsy procedure to radiographically mark the biopsy location.

(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)

David A. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983400

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

*Trademark of United States Surgical Corporation
**Trademark name not yet determined