

APR 25 1998

**IX. 510(k) Summary of Safety and Effectiveness**

K972911

**SUBMITTER:** United States Surgical Corporation  
150 Glover Avenue  
Norwalk, CT 06856

**CONTACT PERSON:** Victor M. Clavelli

**DATE PREPARED:** April 24, 1998

**CLASSIFICATION NAME:** Manual Surgical Instrument for General Use

**COMMON NAME:** Suture Passer

**PROPRIETARY NAME:** Not Yet Determined

**PREDICATE DEVICES:** Modified Endoscopic Suturing\*\* device  
K961173

**DEVICE DESCRIPTION:** The Auto Suture\* SurgiStitch\*\* suture passer is designed to pass either one or both needles of a double armed suture through tissue for the creation of interrupted stitches.

**INTENDED USE:** The Auto Suture\* SurgiStitch\*\* suture passer is indicated for the placement of interrupted sutures for soft tissue approximation in surgical procedures such as cardiovascular and gastrointestinal surgery.

**MATERIALS:** Like all devices manufactured by U.S. Surgical Corporation, the Auto Suture\* SurgiStitch\*\* suture passer is composed entirely of biocompatible materials which are in compliance with ISO 10993-1 for their intended patient contact profile.

\* Trademark of United States Surgical Corporation

\*\* Trademark not yet determined



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 25 1998

Mr. Victor Clavelli  
United States Surgical Corporation  
150 Glover Avenue  
Norwalk, Connecticut 06856

Re: K972911  
Trade Name: Auto Suture SurgiStitch suture passer  
Regulatory Class: II  
Product Code: GAT  
Dated: March 11, 1998  
Received: March 12, 1998

Dear Mr. Clavelli:

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 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

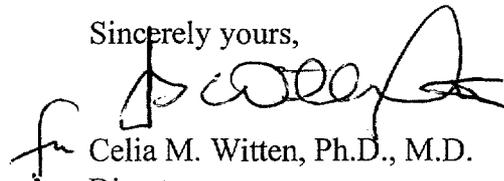
FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used for the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.
2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

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 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594- 4595. 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/dsmamain.html>".

Sincerely yours,



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

**K972911**

**Indications for Use:**

510(k) Number (If known): K972911

Device Name: Auto Suture\* SurgiStitch\*\* suture passer

**Indications for Use:**

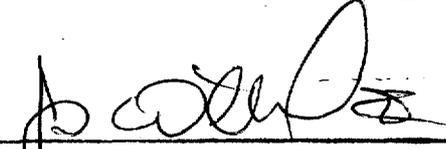
The Auto Suture\* SurgiStitch\*\* suture passer is indicated for the placement of interrupted sutures for soft tissue approximation in surgical procedures such as cardiovascular and gastrointestinal surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X  
Per 21 CFR 801.109

OR Over-The-Counter Use: \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K972911

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\*\* Trademark not yet determined