



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Victor Clavelli
Sr. Associate, Regulatory Affairs
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

JUL 30 1997

Re: K970793
Trade Name: Auto Suture* VCS* Anastomotic** Clip Cartridge
Regulatory Class: II
Product Code: FZP
Dated: July 1, 1997
Received: July 7, 1997

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 (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.

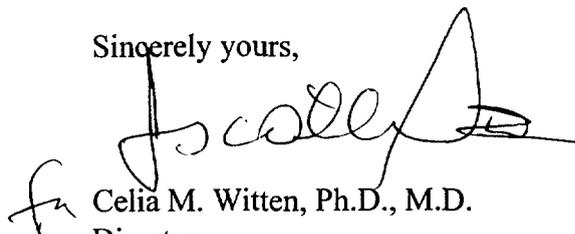
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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) 594-4595. 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,

A handwritten signature in black ink, appearing to read "C. Witten", with a large, stylized flourish extending to the right.

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

Enclosure

K970793

UNITED STATES SURGICAL CORPORATION
510(k) PRE MARKET NOTIFICATION
AUTO SUTURE* VCS* ANASTOMOTIC** CLIP CARTRIDGE



SUMMARY **510(K) SUMMARY OF INFORMATION SUPPORTING SAFETY AND EFFECTIVENESS**

SUBMITTER: United States Surgical Corporation
 150 Glover Avenue
 Norwalk, CT 06856
 (203) 845-1000

JUL 30 1997

CONTACT PERSON: Victor Clavelli

DATE PREPARED: February 28, 1997

CLASSIFICATION NAME: Implantable Clip

COMMON NAME: Implantable Clip

PROPRIETARY NAME: The trademark name of this device has not yet been determined.

PREDICATE DEVICE: AUTO SUTURE* Vascular Anastomosis** clip cartridge

DEVICE DESCRIPTION: The AUTO SUTURE* VCS*Anastomotic** clip cartridge fires multiple titanium clips simultaneously around the junction of 2 vessels to create a vascular anastomosis.

INTENDED USE: The AUTO SUTURE* VCS* Anastomotic** clip cartridge is indicated for the creation of vascular anastomoses.

MATERIALS: The AUTO SUTURE* VCS* Anastomotic** clip cartridge is comprised of materials which are in accordance with ISO Standard #10993-1 for their intended patient contact profile.

PERFORMANCE: The AUTO SUTURE* VCS* Anastomotic**clip cartridge has been subjected to substantial safety and effectiveness testing.

INDICATIONS FOR USE

510(k) Number (if known): K970793

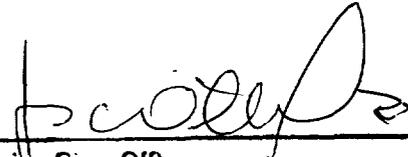
Device Name: AUTO SUTURE* VCS* Anastomotic** clip cartridge

Indications for use:

The AUTO SUTURE* VCS* Anastomotic** clip cartridge is intended to apply titanium clips for use in the creation of vascular anastomoses and in the attachment of synthetic vascular prosthesis.

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

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K970793

Prescription Use: ✓

OR

Over-The-Counter Use: _____