United States Surgical Corporation
510(k) Premarket Notification
AUTO SUTURE* Modified VCS* Clip** Applier

SEP 2 3 1996

SUMMARY OF INFORMATION SUPPORTING K962043 SAFETY AND EFFECTIVENESS:

The AUTO SUTURE* Modified VCS* Clip** device is identical in safety and effectiveness to its currently marketed predicate - U.S. Surgical Corp.'s Vascular Anastomosis Clip** applier - 510(k) #K933887. This clip applier has been marketed for the closure of arteriotomies and venotomies, the attachment of synthetic vascular prosthesis, and the creation of everting anastomoses in blood vessels and other small tubular structures. The performance evaluation of this clip applier by USSC's PreQuality Assurance Laboratory and an independently contracted research laboratory have determined that the clip has additional utility for the approximation of soft tissues such. The information included in this notification demonstrates that the device is substantially equivalent to its predicate in respect to design, function, performance, labeling and sterilization.

- Both the subject and predicate devices are designed to apply a single titanium clip to soft tissues.
- Both the subject and predicate device share the same indications. In addition, the subject device is additionally indicated for the approximation of soft tissues outside of the vascular arena.
- Both the subject devices and other currently marketed United States Surgical Corporation devices are manufactured in the same facilities, using similar processes and controls.
- Both the subject devices and other currently marketed United States Surgical Corporation devices are packaged in the same facilities using similar processes and controls.
- Both the subject and predicate devices perform the exact same function in the same way.
- Both the subject and predicate devices are manufactured from the exact same bio-approved materials

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1996

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

Re: K962043
Trade Name: Auto Suture™ Modified VCS™ Clip™ Applier
Regulatory Class: II
Product Code: FZP and HBT
Dated: August 13, 1996
Received: August 14, 1996

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4595. 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 at (301) 443-6597.

Sincerely yours,

for 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

510(k) Number (if known): K962043

Device Name: Modified VCS* Clip** Applier

Indications For Use:

The AUTO SUTURE* Modified VCS* Clip ** Applier is available in multiple sizes and has application in the closure of arteriotomies and venotomies, the attachment of synthetic vascular prosthesis, the creation of everting anastomosis in blood vessels and other small tubular structures, and for the approximation of prosthetic grafts and dural tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

for (mw) (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K962043

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

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