

UNITED STATES SURGICAL CORPORATION  
510(k) Premarket Notification  
AUTO SUTURE\* Occluding Clamp\*\* Device

K920936

MAY 23 1997

SUMMARY OF INFORMATION SUPPORTING  
SAFETY AND EFFECTIVENESS:

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

**CONTACT PERSON:** Victor Clavelli  
(203) 845-4543

**DATE PREPARED:** October 16, 1996

**CLASSIFICATION NAME:** Vascular Clamp

**COMMON NAME:** AUTO SUTURE\* Occluding Clamp\*\* device

**PROPRIETARY NAME:** Trademark name not yet determined

**PREDICATE DEVICE:** RMI™ YACOUBIAN™ Clamp, K920936

**DEVICE DESCRIPTION:** The AUTO SUTURE\* Occluding Clamp\*\* device is a vascular clamp applier.

**INTENDED USE:** The device is intended for use in those patients undergoing coronary artery bypass surgery when the surgeon determines that it is desirable to temporarily occlude a coronary artery to optimize the exposure during the anastomosis.

**MATERIALS:** The AUTO SUTURE\* Occluding Clamp\*\* device is comprised of materials which are in accordance with ISO Standard # 10993-1.

**PERFORMANCE:** THE AUTO SUTURE\* Occluding Clamp\*\* device was tested both in-vitro and in-vivo to evaluate its performance. The results of the testing demonstrate the subject device to be safe and effective.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 23 1997

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

Re: K964251  
AUTO SUTURE\* Occluding Clamp\*\* Device  
Regulatory Class: II (two)  
Product Code: DXC  
Dated: February 21, 1997  
Received: February 24, 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 (Pre-market 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) 594-4648. 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,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**UNITED STATES SURGICAL CORPORATION  
510(k) Premarket Notification  
AUTO SUTURE\* Occluding Clamp\*\* Device**

**II. INDICATIONS FOR USE:**

510(k) Number (if known): K964251

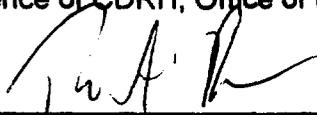
Device Name: AUTO SUTURE\* Occluding Clamp\*\* device

Indications for use: .....

The AUTO SUTURE\* Occluding Clamp\*\* device is intended for use in those patients undergoing coronary artery bypass surgery when the surgeon determines that it is desirable to temporarily occlude a coronary artery to optimize the exposure during the anastomosis.

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Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K964251

Prescription Use: ✓

OR

Over-The-Counter Use: