

K97186f

**United States Surgical Corporation
510(k) Premarket Notification
AUTO SUTURE* Ultrasonic Hand Instrument** system**

IX. 510(k) Summary of Safety and Effectiveness

JUL - 1 1997

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

CONTACT PERSON: Victor Clavelli

DATE PREPARED: May 19, 1997

CLASSIFICATION NAME: Ultrasonic Surgical Instrument

COMMON NAME: Ultrasonic hand instruments

PROPRIETARY NAME: Not yet determined

PREDICATE DEVICES: Ethicon Ultracision ultrasonic hand instruments, K961104

DEVICE DESCRIPTION: The subject instruments consists of three endoscopic hand instruments which connected by an acoustic transducer to a generator. The hand instruments consist of an ultrasonic shear, ultrasonic hook probe and ultrasonic ball probe.

INTENDED USE: The AUTO SUTURE* ultrasonic hand instruments have application in abdominal, pediatric, gynecologic and other open and endoscopic procedures for the transection, dissection and coagulation of tissue(s). The instrument is available with a hook probe, with a shear probe and with a ball probe.

MATERIALS: The AUTO SUTURE* ultrasonic hand instruments are 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 name not yet determined



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL * 1 1997

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

Re: K971861
Trade Name: AUTO SUTURE* Ultrasonic Surgical Instrument
Regulatory Class: II
Product Code: LFL
Dated: May 20, 1997
Received: May 20, 1997

Dear Mr. Clavelli:

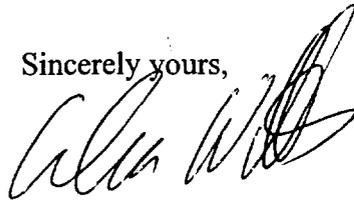
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



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

ENCLOSURE II
Indications For Use:

510(k) Number (if known): K971861

Device Name: AUTO SUTURE* Ultrasonic Surgical Instrument

Indications For Use:

The AUTO SUTURE* ultrasonic hand instruments have application in abdominal, pediatric, gynecologic, thoracic, urologic and general open and endoscopic procedures for the transection, dissection and coagulation of tissue(s). The instrument is available with a hook probe, with a shear and with a ball probe.

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971861