MAR 27 1998

IX. 510(k) Summary of Safety and Effectiveness

SUBMITTER:	United States Surgical Corporation 150 Glover Avenue Norwalk, CT 06856
CONTACT PERSON:	Victor M. Clavelli
DATE PREPARED:	January 13, 1998
CLASSIFICATION NAME:	Natural Nonabsorbable Silk Surgical Suture
COMMON NAME:	Nonabsorbable Silk Suture
PROPRIETARY NAME:	Modified Sofsilk* Suture
PREDICATE DEVICES:	Sofsilk* (K964581)
DEVICE DESCRIPTION:	Modified Sofsilk * Suture is a nonabsorbable, sterile, flexible multifilament thread, prepared from silk fiber produced from the species *Bombyx mori*. The primary component of silk is the high molecular weight fibrous polymer fibroin.
INTENDED USE:	Modified Sofsilk* Suture has indications for use in general soft tissue approximation and/or ligation, including cardiovascular, ophthalmic, microsurgery and neural tissue.
MATERIALS:	All component materials of the Modified Sofsilk* Suture are comprised of materials which are in accordance with ISO Standard # 10993-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 1998

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

Re: K980124

Trade Name: Sofsilk Suture
Regulatory Class: II
Product Code: GAP
Dated: January 13, 1998
Received: January 14, 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 use in general soft tissue and approximation and/or ligation to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Tuesday, October 26, 1993 (Vol. 58, No. 205, Pages 57557 and 57558). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Sofsilk Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

2. This device may not be manufactured from any material other than multifilamentous fibers composed of fibroin, an organic protein that is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Sofsilk Suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) 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) 594-4595. 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,

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

IV. Indications For Use:

510(k) Number (if known): K980124

Name: Modified Sofsilk* Suture

Indications For Use:
Modified Sofsilk* Suture has indications for use in general soft tissue approximation and/or ligation, including cardiovascular, ophthalmic, microsurgery and neural tissue.

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

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR §801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980124