4/1/99

K990951

V. 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:	March 18, 1999
CLASSIFICATION NAME:	Polyglycolic Acid Suture
COMMON NAME:	Polyglycolic Acid Suture
PROPRIETARY NAME:	Maxon**
PREDICATE DEVICES:	Maxon**
DEVICE DESCRIPTION:	Maxon** and Maxon CV** monofilament synthetic absorbable sutures (clear or green) are prepared from a copolymer of glycolic acid and trimethylene carbonate. The sutures are sterile, inert, noncollagenous and nonantigenic.
INTENDED USE:	Maxon** and Maxon CV** sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in pediatric cardiovascular tissue, where growth is expected to occur, and in peripheral vascular tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1999

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

Re: K990951
Trade Name: Maxon and Maxon CV Sterile Synthetic Absorbable Sutures
Regulatory Class: II
Product Code: GAM
Dated: March 19, 1999
Received: March 22, 1999

Dear Mr. Clavelli:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) 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 Friday, May 31, 1991 (Vol. 56, No. 105, Pages 24684 and 24685). 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 devices, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Maxon and Maxon CV sutures are indicated for use in general soft tissue approximation and/or ligation, including use in pediatric cardiovascular tissue, where growth is expected to occur, and in peripheral vascular tissue.

2. These devices may not be manufactured from any material other than homopolymers and copolymers of glycolide and L-lactide. 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 Maxon and Maxon CV surgical sutures. 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 devices.

The sale, distribution and use of these devices is restricted to prescription use in accordance with 21 CFR 801.109.

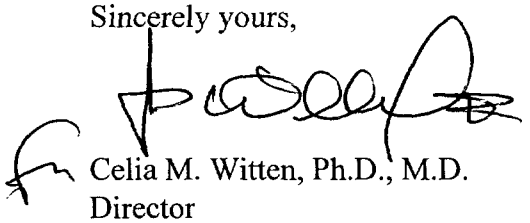
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your devices 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

III. Indications For Use:

510(k) Number (if known): K990951

Device Name: Maxon** Sterile Synthetic Absorbable Suture

Indications For Use:

Maxon and Maxon CV sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in pediatric cardiovascular tissue, where growth is expected to occur, and in peripheral vascular tissue.

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

Concurrence of CDRH, Office of Device 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 K990951