IX. Summary of Safety and Effectiveness

SUBMITTER: United States Surgical,
a division of Tyco Healthcare Group LP
150 Glover Avenue
Norwalk, CT 06856

CONTACT PERSON: Sharon L. Murphy

DATE PREPARED: April 14, 2005

CLASSIFICATION NAME: Nonabsorbable Polypropylene Surgical Suture

COMMON NAME: Modified USS Polypropylene Suture

PROPRIETARY NAME: To be determined

PREDICATE DEVICES: USSC Polypropylene Suture (K954808)
Modified USS Polypropylene Suture (K010909)

INTENDED USE: Modified USS polypropylene sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological surgery.

MATERIALS: Like all the devices manufactured by United States Surgical, a division of Tyco Healthcare Group LP, the Modified USS Polypropylene Suture is composed entirely of biocompatible materials which are in compliance with ISO 10993-1 for their intended patient contact profile.

PERFORMANCE: The performance of the Modified USS Polypropylene Suture is substantially equivalent to the currently marketed USS Polypropylene Suture, which has been successfully used in clinical applications as a wound closure device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 - 2005

Ms. Sharon L. Murphy
Director, Regulatory Affairs
United States Surgical,
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K050947
Trade/Device Name: Modified USS Polypropylene Suture
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAW
Dated: May 3, 2005
Received: May 4, 2005

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Indications for Use

510(k) Number (if known): K050947

Device Name:

Modified USS Polypropylene Suture

Indications For Use:

Modified USS polypropylene sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological surgery.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] Restorative
[illegible] Devices

510(k) Number K050947