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E. 510(K) SUMMARY:

JAN 2 9 2007

Submitter:	United States Surgical, a division of Tyco Healthcare Group, LP 150 Glover Avenue, Norwalk, CT 06856 (203) 845-4515
Contact Person:	Robert Zott, Program Director, Regulatory Affairs
Date Prepared:	January 24, 2007
Device Classification Name:	Absorbable poly(glycolide/L-lactide) surgical suture
Device Common Name:	Surgical Suture
Device Proprietary Name:	Polysorb* Synthetic Absorbable Suture with Modified Packaging (Note: The trade name for the packaging is yet to be determined.)
Predicate Device(s):	K981935: Modified Polysorb* Suture (manufactured by U.S. Surgical, a division of Tyco Healthcare Group, LP)
Device Description:	Polysorb* Synthetic Absorbable Suture with Modified Packaging shall remain identical to the predicate device, an absorbable poly(glycolide/L-lactide) surgical suture, with the addition to the packaging of an injection port to the inner foil pouch.
Technological Characteristics:	The injection port shall enable the injection of sterile saline (0.9% NaCl) into the pouch for pre-wetting of the suture under sterile conditions prior to use.
Performance Data:	In-vitro studies were performed in accordance with the Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA, issued on June 3, 2003 to demonstrate that the functional performance of the suture is substantially equivalent to the predicate device when pre-wetted with sterile saline (0.9% NaCl) using the injection port for up to 12 hours at room temperature prior to use.
Indications:	The device is indicated for use in soft tissue approximation or ligation and ophthalmic surgery, but not in cardiovascular or neural tissue.
Materials:	Coated glycolide and lactide copolymer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tyco Healthcare Group, LP
% Mr. Robert Zott
Program Director, Regulatory Affairs
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

JAN 29 2007

Re: K063536
Trade/Device Name: Absorbable poly(glycolide/L-lactide) Surgical suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: November 22, 2006
Received: November 22, 2006

Dear Mr. Zott:

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) 276-0120 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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D. STATEMENT OF INDICATIONS FOR USE:

510(k) Number (if known): K063536

Device Name: Polysorb* Synthetic Absorbable Suture with Modified Packaging
(Note: The trade name for the packaging is yet to be determined.)

Indications For Use: Polysorb* Synthetic Absorbable Suture with Modified Packaging is indicated for use in soft tissue approximation or ligation and ophthalmic surgery, but not in cardiovascular or neural 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, and Neurological Devices

510(k) Number K063536

* Polysorb is a trademark of United States Surgical, a division of Tyco Healtchcare Group, LP