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JAN 2 8 2002

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS SUBSTANTIAL EQUIVALENCY

Submitter: Address:	Surgical Specialties Corporation 100 Dennis Drive Reading, PA 19606
Telephone: Contact Person:	610 404 1000, ext. 2231 Elizabeth Lazaro Regulatory Affairs Specialist
Date Prepared:	December 3, 2001

Name of Device:	Sharpoint® Coated ***FAST ABSORBING***™ PolyGlycolic Acid braided, synthetic absorbable suture, undyed.
Common / Usual Classification Name:	Suture, Absorbable, Synthetic, PolyGlycolic Acid

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Predicate Device:	Ethicon, Inc. Coated VICRYL *RAPIDE* (polyglactin 910) braided synthetic absorbable, suture, undyed.

Device Description	Coated ***FAST ABSORBING*** PolyGlycolic Acid Suture is a synthetic absorbable braided, sterile, surgical suture composed of a homopolymer of Glycolic Acid. The suture material is coated with a copolymer of Polycaprolactone and PolyGlycolic Acid. The substances contained in the coating and suture are noncollagenous and nonantigenic.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Intended Use:	Coated ***FAST ABSORBING*** PolyGlycolic Acid suture is indicated only for use in superficial general soft tissue approximation of the skin and mucosa where only short-term wound support (7–10 days) is required. Coated ***FAST ABSORBING*** PolyGlycolic Acid suture is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures. The coated ***FAST ABSORBING*** PolyGlycolic Acid suture, undyed has the same intended use as the predicate device.
Technological Characteristics:	Coated ***FAST ABSORBING*** PolyGlycolic Acid suture, undyed is composed of 100% PolyGlycolic Acid, a material equivalent to the material comprising the predicate VICRYL Rapide device. The suture has the same design as the VICRYL Rapide predicate devices, being a sterile, flexible suture available in a coated braided multifilament form.
Performance Data:	Physical testing was conducted on the Coated ***FAST ABSORBING*** PolyGlycolic Acid suture to USP 24, including <861> *Sutures – Diameter*, <871> *Sutures- Needle Attachment*, and <881> *Tensile Strength*. Animal testing was performed for conformance to ISO 10993 for biocompatibility and implant studies in animals to demonstrate rates of tensile strength and mass loss.

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Substantial Equivalence	The ***FAST ABSORBING*** PolyGlycolic Acid Synthetic Absorbable surgical suture is similar in intended use, materials, design, and performance characteristics to the Ethicon VICRYL Rapide Synthetic Absorbable Surgical Suture (K944110). The determination of substantial equivalence for this device was based on a detailed device description, physical testing (U.S.P. 24) and animal testing for conformance with performance standards e.g. ISO 10993-1 Biological Evaluation of Medical Devices and the FDA Guidance Document for Surgical Suture 510(k)s issued on August 10, 2000. Based on the 510(k) summaries (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2002

Ms. Elizabeth Lazaro
Regulatory Affairs Specialist
Surgical Specialties Corporation
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K014021
Trade/Device Name: Sharpoint® Coated FAST ABSORBING™ Polyglycolic Acid Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(glycolide/L-lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: December 05, 2001
Received: December 06, 2001

Dear Ms. Lazaro:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): K014021

Device Name: Sharpoint® Coated *FAST ABSORBING*™ PolyGlycolic Acid Synthetic

Absorbable Surgical Suture

Indications for Use:

Sharpoint® Coated *Fast Absorbing*™ PolyGlycolic Acid Suture is indicated only for use in superficial soft tissue approximation of the skin and mucosa where only short term wound support (7 – 10 days) is required. Coated *Fast Absorbing*™ PolyGlycolic Acid Suture is not intended for use in ligation, ophthalmic cardiovascular or neurological procedures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014021