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SECTION 8

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

MODIFIED DEVICE NAME: Coated VICRYL* (Polyglactin 910) Synthetic Absorbable Suture

PREDICATE DEVICES NAME: Coated VICRYL* (Polyglactin 910) Synthetic Absorbable Suture.

Device Description

Modified Coated VICRYL* (Polyglactin 910) suture is a synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. Modified Coated VICRYL* suture, which is prepared by coating VICRYL* suture material with a copolymer of 90% caprolactone and 10% glycolide and subsequently with a mixture composed of equal parts of a copolymer of glycolide and lactide (Polyglactin 370) with calcium stearate.

Intended Use

Modified Coated VICRYL* suture is intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

Modified Coated VICRYL* suture has the same intended use as the predicate device, current Coated VICRYL* suture.

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Indications Statement

Modified Coated VICRYL* suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

Technological Characteristics

The new device has similar technological characteristics as the predicate devices. Like the predicate device, it is a sterile, braided synthetic absorbable suture that conforms to the USP Monograph for absorbable surgical sutures, except for diameter.

Performance Data

Non-clinical laboratory testing was performed demonstrating that the device conformed to the USP Monograph for absorbable surgical sutures. Additionally, in-vivo testing was provided showing that the device performed as intended.

Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Devices under the Federal Food, Drug, and Cosmetic Act.

Contact

Lea Ann Conway
Director, Regulatory Affairs and Quality Assurance
Ethicon Products
ETHICON, Inc.
Rt. #22, West
Somerville, NJ 08876-0151

Date

July 10, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2002

Ethicon, Inc
Lea Ann Conway
Director, Regulatory Affairs and Quality Assurance
Route 22, West
Somerville, New Jersey 08876

Re: K022269
Trade/Device Name: Coated VICRYL* (Polyglactin 910) Synthetic Absorbable Suture
Regulation Number: 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: July 10, 2002
Received: July 15, 2002

Dear Ms. Conway:

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" (21 CFR 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,

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

INDICATIONS FOR USE

510(k) Number (if known): K022269

Device Name: Coated VICRYL* (Polyglactin 910) Synthetic Absorbable Suture

Indications for Use: Coated VICRYL* suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-9G)

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

510(k) Number K022269

* Trademark