



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 18 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

John D. Paulson, Ph.D.
Director, Regulatory Affairs
Ethicon, Inc.
P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K944110
VICRYL™ Rapide Suture
Regulatory Class: II
Dated: November 29, 1994
Received: November 30, 1994

Dear Dr. Paulson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent 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 Wednesday, September 18, 1991 (Vol. 56, No. 18, Pages 47150 and 47151). 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 device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Vicryl™ Rapide Suture is indicated only for use in superficial soft tissue approximation of skin and mucosa where only short-term wound support (7-10 days) is required. Vicryl™ Rapide Suture is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.
2. This device may not be manufactured from any material other than homopolymers and copolymers made from glycolide and/or L-lactide. Any deviation of the polymer composition or processing as described in this 510(k) notification must be submitted to FDA in a new premarket notification at least 90 days prior to implementation of the proposed changes. 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 Vicryl™ Rapide surgical suture. 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 device.

The sale, distribution and use of this device are 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 device 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 device 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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a reclassified transitional device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other

2

Page 3 - John D. Paulson, Ph.D.

general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

3

510(k) SUMMARY

SUBSTANTIAL EQUIVALENCE OF VICRYL* RAPIDE (POLYGLACTIN 910) BRAIDED COATED SYNTHETIC ABSORBABLE SUTURE, UNDYED TO COATED VICRYL* (POLYGLACTIN 910) SYNTHETIC ABSORBABLE SUTURE

This 510(k) Summary demonstrates that VICRYL *rapide* suture is substantially equivalent in design and composition to the currently marketed Coated VICRYL suture. VICRYL *rapide* suture is also substantially equivalent to currently marketed ETHICON* surgical gut (plain) suture in surgical performance.

NEW DEVICE: VICRYL *rapide* Braided Coated Synthetic Absorbable Suture, undyed

VICRYL *rapide* suture, undyed is a sterile suture, flexible multifilament strand prepared from a copolymer made from glycolide and lactide. The coating for VICRYL *rapide* suture is prepared with a mixture of a copolymer of glycolide and L-lactide and calcium stearate. VICRYL *rapide* suture is intended for use in soft tissue approximation, (i.e., mucosa and skin), where only short term wound support is required and where the rapid absorption of the suture would be beneficial. ETHICON GmbH & Co KG, Germany has conducted a clinical study to demonstrate the surgical performance of VICRYL *rapide* suture. The evaluations were conducted in a variety of surgical procedures that included episiotomies, cutaneous skin closure and circumcisions. In this study, overall performance was good for VICRYL *rapide* suture with special emphasis on favorable cosmetic results and the fact that suture removal is often not required.

VICRYL *rapide* suture is made from the same copolymer composition as the predicate device. VICRYL *rapide* suture was evaluated in a variety of biocompatibility studies. The results of these studies did not raise any new safety and effectiveness concerns. VICRYL *rapide* suture will be sterilized by Cobalt-60 irradiation to a minimum Sterility Assurance Level (SAL) of 10^{-6} . The packaging consists of an inner paper folder placed within a sealed labeled foil package. This package is then enveloped in an overwrap pouch. Secondary packaging consisting of sales cartons and corrugated shipping containers will be used to protect the product and package during storage and distribution.

PREDICATE DEVICE: Coated VICRYL suture is a sterile, synthetic absorbable suture intended for clinical use in soft tissue approximation and/or ligation including ophthalmic surgery. ETHICON* surgical (plain) gut suture is intended for use in soft tissue approximation and/or ligation including ophthalmic surgery. Except for clinical use in ligation and ophthalmic surgery, and use of VICRYL *rapide* suture where only short term wound support is required, VICRYL *rapide* suture and Coated VICRYL suture both have the same clinical use in that they are intended for use in all types of soft tissue approximation.

Both VICRYL *rapide* sutures and Coated VICRYL sutures are fabricated from the same copolymer of glycolide and L-lactide and coating that consists of a copolymer of glycolide, lactide and calcium stearate. Both VICRYL *rapide* suture and Coated VICRYL suture use the same component materials that are recognized as being safe as surgical implant materials.

Based on the information in this summary, it can be concluded that within its indications for use, VICRYL *rapide* suture is substantially equivalent in surgical performance to ETHICON surgical (plain) gut suture and in design and composition to Coated VICRYL suture.

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126