K974299

FEB 13 1998

SECTION 7

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: Modified ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed

PREDICATE DEVICE: Existing Cleared Device - Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed.

REFERENCE DEVICE NAMES: Johnson & Johnson Absorbable Tendon Suture and Coated VICRYL* II (Polyglactin 910) suture.

510(k) SUMMARY

Device Description

Modified ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed is a synthetic braided absorbable surgical suture prepared from a copolymer of lactide and glycolide. The suture is coated with a copolymer of caprolactone and glycolide.

Continued on next page

510(K) SUMMARY, Continued

Intended Use	Modified ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed is intended for use in general soft tissue approximation and/or ligation as is the predicate device ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed. Modified Absorbable poly(L-lactide/glycolide Surgical Suture, Undyed is indicated for orthopedic uses including tendon and ligament repairs and reattachment to bone.
Indications Statement	Modified ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed is indicated for soft tissue approximation and/or ligation, and orthopedic uses including tendon and ligament repairs and reattachment to bone but not for use in ophthalmic, cardiovascular, or neurological tissue.
Technological Characteristics	The modified device has the same technological characteristics as the predicate device (existing device) ETHICON Absorbable poly(L-lactide/glycolide Surgical Suture, Undyed.
Performance Data	Nonclinical laboratory testing was performed to determine breaking strength retention. Biocompatibility and Functionality testing was conducted to assess the safety and effectiveness of Modified ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed. Results indicated that the device was highly biocompatable and was functional within its indicated uses.

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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	Gregory Jones Director, Regulatory Affairs ETHICON, Inc. Rt. #22, West Somerville, NJ 08876-0151
Date	November 14, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 1998

Mr. Gregory Jones
Director, Regulatory Affairs
Ethicon, Inc.
P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K974299
Panacryl Absorbable poly (L-lactide/glycolide) Surgical Suture, Undyed
Regulatory Class: II
Product Code: GAM
Dated: November 14, 1997
Received: November 17, 1997

Dear Mr. Jones:

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 (for the indications for use stated in the enclosure) 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 Friday, May 31, 1991 (Vol. 56, No. 105, Pages 24684 and 24685). 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 Panacryl Absorbable poly (L-lactide/glycolide) Surgical Suture, Undyed 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 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 Panacryl Absorbable poly

(L-lactide/glycolide) Surgical Suture, Undyed 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 will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the

Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

INDICATION FOR USE

510(k) Number (if known): K974299

Device Name: Modified ETHICON Absorbable poly(L-lactide/glycolide) Surgical Suture, Undyed

Indications for Use: Modified ETHICON Absorbable poly(L-lactide/glycolide) Surgical Sutures, Undyed are indicated for use in general soft tissue approximation and/or ligation, and orthopedic uses including tendon and ligament repairs and reattachment to bone but not for use in ophthalmic, cardiovascular or neurological tissues. The Modified ETHICON Absorbable poly(l-lactide/glycolide Surgical Suture, is particularly useful where extended wound support (up to 6 months) is desirable.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974299

(Optional Format 1-2-9G)