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JMP-2005-008

JUN 29 2005

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.

Submitted by:

Jennifer M. Paine
Sr. Project Manager, Regulatory Affairs
Ethicon, Inc., A *Johnson & Johnson* Company
Route 22 West, PO Box 151
Somerville, NJ 08876

Name/Classification of Device:

Class II in 21 CFR § 878.4493, Absorbable poly(glycolide/l-lactide) surgical suture (GAM) and § 878.4830, Absorbable surgical gut suture (GAN)

Trade Name:

MONOCRYL* Plus (Poliglecaprone 25) Antibacterial Suture

Predicate Devices:

MONOCRYL* (poliglecaprone 25) Suture (K960653 and K964072)
VICRYL* Plus Antibacterial Suture (K032420)

Statement of Intended Use:

MONOCRYL* Plus Antibacterial sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Device Description:

MONOCRYL* Plus Antibacterial (poliglecaprone 25) suture is a monofilament synthetic absorbable surgical suture prepared from a copolymer of glycolide and epsilon-caprolactone. The suture is available dyed (D&C Violet No. 2) or undyed (natural). The suture contains Irgacare MP** (triclosan), a broad-spectrum antibacterial agent, at no more than 2360 μg/m.

Summary of Technological Characteristics of New Device to Predicate Devices:

The modified device has similar technological characteristics as the predicate devices. Like currently marketed MONOCRYL* Suture, it is a sterile, monofilament synthetic absorbable suture that conforms to the USP

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Monograph for absorbable surgical sutures, except for diameter. Like the currently marketed Coated VICRYL Plus Antibacterial suture, the modified device contains Irgacare** MP, an antibacterial agent.

Performance Data:

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

Conclusions:

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

** Trademark of Ethicon, Inc.*
***Trademark of Ciba Specialty Chemicals Corporation.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

Ms. Jennifer M. Paine
Senior Project Manager, Regulatory Affairs
Ethicon Incorporated
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

Re: K050845
Trade/Device Name: MONOCRYL* Plus Antibacterial (Poliglecaprone 25) Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L- lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: April 1, 2005
Received: April 4, 2005

Dear Ms. Paine:

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.

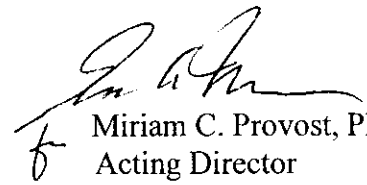
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115 . 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K050845

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Indications for Use

510(k) Number (if known): _____

Device Name: MONOCRYL* Plus Antibacterial (Poliglecaprone 25) Suture

Indications for Use:

MONOCRYL* Plus Antibacterial (poliglecaprone 25) sutures (dyed or undyed) are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Prescription Use X . (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K050845