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SECTION 2 – 510(k) SUMMARY

ORTHOCORD Suture

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062
Contact Person	Ruth C. Forstadt Senior Regulatory Affairs Associate DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062 Telephone: 781-251-3188 Facsimile: 781-278-9578 e-mail: rcforstad@ethus.jnj.com
Name of Medical Device	Classification Name: Non-absorbable poly(ethylene terephthalate) surgical suture; and Suture, Surgical, Absorbable, Polydioxanone Common/Usual Name: Suture Proprietary Name: ORTHOCORD Suture
Substantial Equivalence	ORTHOCORD Suture is substantially equivalent to: PDS II suture (N18331) manufactured by Ethicon, Inc. and FiberWire suture (K010673) manufactured by Arthrex, Inc.
Device Classification	Sutures are classified by the FDA as Class II Medical Devices. PDS Suture carries an FDA product code NEW, and is classified as absorbable surgical suture, polydiaxanone under 21 CFR 878.4840. Polyethylene suture carries an FDA product code GAT, and is classified under 21 CFR 878.5000.
Device Description	ORTHOCORD suture is a synthetic, sterile, braided composite suture composed of dyed (D&C Violet #2) absorbable polydioxnone (PDS) and un-dyed non-absorbable polyethylene. The partially absorbable suture is coated with a copolymer of 90% caprolactone and 10% glycolide.

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Indications for Use	ORTHOCORD Suture is indicated for use in general soft tissue approximation and/or ligation, including use in orthopedic surgeries.
Safety and Performance	The determination of substantial equivalence for this device was based on a detailed device description, and conformance to consensus and voluntary standards. Non-clinical laboratory testing was performed demonstrating that the device conformed to the USP monograph for absorbable sutures. Based on the indications for use, technological characteristics, and comparison to predicate devices, the Mitek ORTHOCORD Suture has been shown to be substantially equivalent to predicate devices 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

APR 1 3 2004

Ms. Ruth C. Forstadt
Senior Regulatory Affairs Associate
DePuy Mitek
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K040004
Trade/Device Name: Orthocord Suture
Regulation Number: 21 CFR 878.4840, 878.5000
Regulation Name: Absorbable PDS suture, Nonabsorbable polyethylene suture
Regulatory Class: II
Product Code: NEW, GAT
Dated: March 31, 2004
Received: April 1, 2004

Dear Mrs. Forstadt:

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 (301) 594-4659. 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/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

K040004

Indications for Use

510(k) Number (if known): K040004

Device Name: ORTHOCORD Suture

Indications for Use:

ORTHOCORD Suture is indicated for use in general soft tissue approximation and/or ligation, including use in orthopedic surgeries.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K040004