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510(k) Summary – BioKnotless RC Anchor

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson Company 249 Vanderbilt Avenue Norwood, MA 02062
Contact Person	Allyson Barford Regulatory Affairs Associate DePuy Mitek a Johnson & Johnson Company 249 Vanderbilt Avenue Norwood, MA 02062 Telephone: 781-251-2794 Facsimile: 781-278-9578 e-mail: abarford@dpyus.jnj.com
Name of Medical Device	Classification Name: Screw, Fixation, Bone Staple Common/Usual Name: Appliance for reconstruction of bone to soft tissue Proprietary Name: BioKnotless RC Anchor
Device Classification	Screw, Fixation, Bone Staple devices have been classified as Class II, GAM and MAI according to 21 CFR 888.3030. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Screw, Fixation, Bone Staple devices.
Indications for Use	The Mitek BIOKNOTLESS RC Anchor is indicated for use in soft tissue to bone fixation in association with adequate post-operative immobilization as follows: **Shoulder:** Rotator cuff repair.
Device Description	The BioKnotless RC anchor is a preloaded absorbable disposable suture anchor/inserter assembly designed to allow soft tissue repair to bone without the need for knot tying. The suture assembly is made up of a non-absorbable Ethibond or Panacryl anchor loop and a utility loop constructed of non-absorbable Ethibond Excel suture (green,

	#2/0). The Ethibond and Panacryl sutures are manufactured by Ethicon, Inc. The absorbable anchor is a one-piece suture anchor constructed of molded Poly(L-lactide) polymer.
Substantial Equivalence	Based on the type of changes being made and the fact that the BioKnotless RC represents the same fundamental scientific technology as the existing BioKnotless Anchor (K002639) and Panalok RC Anchor (K964013); Mitek believes the BioKnotless RC Anchor is substantially equivalent to the BioKnotless Anchor (K002639) and Panalok RC Anchor (K964013) manufactured by DePuy Mitek.
Safety	Biocompatibility studies have demonstrated the BioKnotless RC Anchor to be non-toxic, non-irritating, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 3 2004

Ms. Allyson Barford
Regulatory Affairs Associate
Depuy Mitek
a Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K041064
Trade/Device Name: BioKnotless RC Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR and MAI
Dated: April 5, 2004
Received: April 23, 2004

Dear Ms. Barford:

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 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,

for Mark N Melkerson

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): K041064

Device Names:

BioKnotless RC Anchor

Indications for Use:

The Mitek BIOKNOTLESS RC Anchor is indicated for use in soft tissue to bone fixation in association with adequate post-operative immobilization as follows:
Shoulder: Rotator cuff repair.

Mark N Milham

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

510(k) Number K041064

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes or Over-the-Counter Use No