K070925

510(k) SUMMARY

MAY - 2 2007

Bioknotless BR Anchor / Lupine BR Anchor

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767
Contact Person	Kristine Christo Senior Regulatory Affairs Specialist DePuy Mitek a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767 Telephone: 508-828-3359 Facsimile: 508-977-6955 e-mail: KChristo@Dpyus.jnj.com
Name of Medical Device	Classification Name: Screw, Fixation, Bone Staple Common/Usual Name: Appliance for reconstruction of soft tissue to bone Proprietary Name: Bioknotless Anchor / Lupine Anchor
Substantial Equivalence	Bioknotless BR Anchor is substantially equivalent to: Bioknotless Plus Anchor, K062170, manufactured by DePuy Mitek. RapideLupine Anchor is substantially equivalent to: Lupine Plus Anchor, K062170, manufactured by DePuy Mitek
Device Classification	Bone anchors/screws are classified by the FDA as Class II Medical Devices under the generic category of Single/Multiple component metallic bone fixation appliances and accessories. Bioknotless Anchor / Lupine Anchor Systems carry FDA product code MAI and is classified as single / multiple component metallic bone fixation appliances and accessories soft tissue fastener under 21 CFR 888.3030.
Device Description	Bioknotless BR Anchor / Lupine BR are a preloaded, disposable

suture anchors/ inserters assembly for soft tissue repair to bone in the shoulder, knee, ankle, foot, and elbow. The anchor is dimensionally identical anchor to that of the Bionotless Anchor Plus / Lupine Anchor Plus. The anchor material is changing from absorbable polylactic acid (PLA) in the predicate device to Biocryl Rapid, a β-TCP/PLGA biocomposite material in the proposed devise. The anchor is a one piece suture anchor sold with Ethibond Suture (NDA 17-804 and 17-809), Panacryl Suture (K964345), or Orthocord Suture (K040004 and K043298).
Biocryl Rapid, a β-TCP/PLGA biocomposite material is currently used in the Mitek Milagro Screw (K032717, K060830) which is indicated for the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee. Additionally, the 7, 8 and 9 mm x23 mm Mitek Milagro screws are indicated for: medial and lateral collateral ligament repair of the knee, proximal bicep tenodesis in the shoulder and distal bicep tenodesis in the elbow.

Indications for Use

The Bioknotless Anchor is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows: OPEN PROCEDURES SHOULDER: 1. Bankart repair
2. SLAP lesion repair; 3. Rotator cuff repair; 4a. Capsule shift/capsulo-labral reconstruction, at the anterior glenoid rim site; 4b. Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus; 5. Biceps tenodesis
6. Acromio-clavicular separation; 7. Deltoid repair
ELBOW: 1. Biceps tendon reattachment; 2. Tennis elbow repair
ANKLE:1. Achilles tendon repair/reconstruction; 2. Lateral stabilization
3. Medial stabilization at the medial talus site; Foot: Hallux Valgus reconstruction; 4. Midfoot reconstruction
KNEE: 1. Medial collateral ligament repair; 2. Lateral collateral ligament repair; 3. Joint capsule closure to anterior proximal tibia; 4. Posterior oblique ligament or joint capsule to tibia repair; 5. Extra capsular reconstruction / ITB tenodesis; 6. Patellar ligament and tendon avulsion repairs.
ARTHROSCOPIC PROCEDURES SHOULDER; 1. Bankart repair
2. SLAP lesion repair; 3. Rotator cuff repair; 4. Capsule shift repair (glenoid rim)

The Lupine Anchor is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows:
OPEN PROCEDURES SHOULDER:1. Bankart repair,2. SLAP lesion repair
3. Rotator cuff repair, 4a. Capsule shift/capsulo-labral reconstruction, at the anterior glenoid rim site, 4b. Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus, 5. Biceps tenodesis, 6. Acromio-clavicular separation, 7. Deltoid repair
ELBOW: 1. Biceps tendon reattachment, 2. Tennis elbow repair
ANKLE: 1. Achilles tendon repair/reconstruction, 2. Lateral stabilization
3. Medial stabilization at the medial talus site, Foot: Hallux Valgus reconstruction, 4. Midfoot reconstruction
KNEE:1. Medial collateral ligament repair, 2. Lateral collateral ligament repair
3. Joint capsule closure to anterior proximal tibia., 4. Posterior oblique ligament or joint capsule to tibia repair, 5. Extra capsular reconstruction / ITB

	tenodesis, 6. Patellar ligament and tendon avulsion repairs. ARTHROSCOPIC PROCEDURES SHOULDER:1. Bankart repair, 2. SLAP lesion repair, 3. Rotator cuff repair, 4. Capsule shift repair (glenoid rim)
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. Bench testing was performed demonstrating that the Bioknotless BR Anchor / Lupine BR Anchor met predetermined acceptance criteria. Based on the indications for use, technological characteristics, and comparison to predicate devices, the Bioknotless BR Anchor and Rapide Lupjne Anchor 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

DePuy Mitek, a Johnson
& Johnson Company
% Ms. Kristine Christo
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

MAY - 2 2007

Re: K070925
Trade/Device Names: Bioknotless BR Anchor
Lupine BR Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI, GAM, GAS, GAT
Dated: April 2, 2007
Received: April 3, 2007

Dear Ms. Christo:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices 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 devices comply 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 devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K070925

Device Names: Bioknotless BR Anchor

Indications for Use: The Bioknotless BR Anchor with is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows:

OPEN PROCEDURES SHOULDER
1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4a. Capsule shift/capsulo-labral reconstruction, at the anterior glenoid rim site
4b. Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus
5. Biceps tenodesis
6. Acromio-clavicular separation
7. Deltoid repair

ELBOW
1. Biceps tendon reattachment
2. Tennis elbow repair

ANKLE
1. Achilles tendon repair/reconstruction
2. Lateral stabilization
3. Medial stabilization at the medial talus site

Foot: Hallux Valgus reconstruction
4. Midfoot reconstruction

KNEE
1. Medial collateral ligament repair
2. Lateral collateral ligament repair
3. Joint capsule closure to anterior proximal tibia
4. Posterior oblique ligament or joint capsule to tibia repair
5. Extra capsular reconstruction / ITB tenodesis
6. Patellar ligament and tendon avulsion repairs.

ARTHROSCOPIC PROCEDURES SHOULDER
1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4. Capsule shift repair (glenoid rim)

Prescription Use ____√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K070925

INDICATIONS FOR USE

510(k) Number (if known): K070925

Device Names: Lupine BR Anchor

INDICATIONS FOR USE: The Lupine BR Anchor is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows:

OPEN PROCEDURES SHOULDER
1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4a. Capsule shift/capsulo-labral reconstruction, at the anterior glenoid rim site
4b. Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus
5. Biceps tenodesis
6. Acromio-clavicular separation
7. Deltoid repair

ELBOW
1. Biceps tendon reattachment
2. Tennis elbow repair

ANKLE
1. Achilles tendon repair/reconstruction
2. Lateral stabilization
3. Medial stabilization at the medial talus site

Foot: Hallux Valgus reconstruction
4. Midfoot reconstruction

KNEE
1. Medial collateral ligament repair
2. Lateral collateral ligament repair
3. Joint capsule closure to anterior proximal tibia
4. Posterior oblique ligament or joint capsule to tibia repair
5. Extra capsular reconstruction / ITB tenodesis
6. Patellar ligament and tendon avulsion repairs.

ARTHROSCOPIC PROCEDURES
SHOULDER
1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4. Capsule shift repair (glenoid rim)

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)