K090669 #1/3

510(k) Summary

APR - 3 2009

RigidFix Biocryl Cross Pin Kit

Submitter's Name and Address:

DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767, USA

Contact Person

Zheng Liu
Regulatory Affairs Specialist
DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767, USA
Telephone: 508-977-3966
Facsimile: 508-977-6955
e-mail: zliu8@its.jnj.com

Name of Medical Device

Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Common/Usual Name:	Bone Anchor
Proprietary Name:	RigidFix Biocryl Cross Pin Kit

Substantial Equivalence

The **RigidFix Biocryl Cross Pin Kit** is substantially equivalent to:

- RigidFix Cross Pin Kits (PLA)
  - K013781 RigidFix 2.7 mm BTB Cross Pin Kit (February 02, 2002)
  - K010633 RigidFix Tibial ACL Cross Pin System (May 09, 2001)
  - K974341 Mitek ST Absorbable (PLA) Cross Pin (April 16, 1998)
  - K974291 Mitek BTB Absorbable (PLA) Cross Pin (March 03, 1998)
- K032167 BioIntrafix Tibial Tapered Sheaths and Screws (October 15, 2003)
- K013572 Biocryl Interference Screws (March 14, 2002)

Device Classification

Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MAI, and subsequent code HTY, regulated under 21 CFR 888.3030.

K090669 #2/3

Device Description

The proposed **RigidFix Biocryl 2.7 mm BTB Cross Pins** are absorbable implants manufactured from "Biocryl" (15% β-TCP/85%PLA) material. The proposed RigidFix Biocryl 2.7 mm BTB Cross Pins are used for the fixation of bone-tendon-bone grafts to the femur and the tibia in Anterior Cruciate Ligament (ACL) reconstruction. A total of four RigidFix Biocryl 2.7 mm BTB Cross Pins are used to complete the reconstruction: two on the femur and two on the tibia.

The proposed **RigidFix Biocryl Femoral 3.3 mm ST Cross Pins** are absorbable implants manufactured from "Biocryl" (15% β-TCP/85%PLA) material. The proposed RigidFix Biocryl Femoral 3.3 mm ST Cross Pins are used for the fixation of soft tissue (semitendinosus and gracillis) grafts to the femur in ACL reconstruction. Two RigidFix Biocryl Femoral 3.3 mm ST Cross Pins are used to complete the repair.

The proposed **RigidFix Biocryl Tibial 3.3 mm ST Cross Pins** are absorbable implants manufactured from "Biocryl" (15% β-TCP/85%PLA) material. The proposed RigidFix biocryl Tibial 3.3 mm ST Cross Pins are used for the fixation of soft tissue (semitendinosus and gracillis) grafts to the femur in ACL reconstruction. Two RigidFix Biocryl Tibial 3.3 mm ST Cross Pins are used to complete the repair.

Each RigidFix Biocryl Cross Pin Kit is provided sterile and is for single patient use only.

Except for the Interlocking Trocar and Sleeve assemblies that are packaged in the RigidFix kits with the RigidFix Biocryl pins, other reusable instrumentation is offered separately to assist in the placement of the RigidFix Biocryl pins. The instrumentation consists of Tibial Guide Frame, Tibial Rods, Long Stepped Trocar, Trocar Trial, Guide Block Head Thumb Screw, Probe, Short Stepped Trocar, Tibial Pin Insertion Rod and Femora/Tibial Rod Thumb Screw. These devices are all stainless steel, non-sterile, reusable devices.

Indications for Use

The **RigidFix Biocryl 2.7 mm BTB Cross Pin Kit** is intended for femoral and/or tibial fixation of autograft or allograft ACL Bone-tendon-bone grafts.

The **RigidFix Biocryl Femoral 3.3 mm ST Cross Pin Kit** is intended for femoral fixation of autograft or allograft ACL soft tissue grafts (semitendinosus and gracillis).

The **RigidFix Biocryl Tibial 3.3 mm ST Cross Pin Kit** is intended for tibial fixation of autograft or allograft ACL soft tissue grafts (semitendinosus and gracillis).

K090669 #3/3

Safety and Performance

In support of the 510(k), Mitek has provided certification of compliance to 21 CFR 820.30 Design Control requirements, descriptions of Mitek's subcontractor Design Control and Risk Analysis procedures, and the results of validation testing (performance testing) for the device modification.

Based on the Indications for Use, technological characteristics and safety and performance testing, the **RigidFix Biocryl Cross Pin Kit** 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 - 3 2009

DePuy Mitek
% Ms. Zheng Liu
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K090669
Trade/Device Name: RigidFix Biocryl Cross Pin Kits
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI, HTY
Dated: March 11, 2009
Received: March 13, 2009

Dear Ms. Liu:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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): K090669

Device Name: RigidFix Biocryl Cross Pin Kit

Indications for Use:

The **RigidFix Biocryl 2.7 mm BTB Cross Pin Kit** is intended for femoral and/or tibial fixation of autograft or allograft ACL Bone-tendon-bone grafts.

The **RigidFix Biocryl Femoral 3.3 mm ST Cross Pin Kit** is intended for femoral fixation of autograft or allograft ACL soft tissue grafts (semitendinosus and gracillis).

The **RigidFix Biocryl Tibial 3.3 mm ST Cross Pin Kit** is intended for tibial fixation of autograft or allograft ACL soft tissue grafts (semitendinosus and gracillis).

Prescription Use ____x___ 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 K090669