K091041

SECTION 2 – 510(k) SUMMARY

RigidFix Biocryl Cross Pin Kits
BioIntrafix Tibial Tapered Sheaths and Screws
Biocryl Interference Screws

AUG 07 2009

Submitter's Name and Address:

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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 Kits
BioIntrafix Tibial Tapered Sheaths and Screws
Biocryl Interference Screws

Substantial Equivalence

RigidFix Biocryl Cross Pin Kits are substantially equivalent to:

- K090669 RigidFix Biocryl Cross Pin Kits (April 03, 2009).

BioIntrafix Tibial Tapered Sheaths and Screws are substantially equivalent to:

- K032167 BioIntrafix Tibial Tapered Sheaths and Screws (October 15, 2003).

Biocryl Interference Screws are substantially equivalent to:

- K013572 Biocryl Interference Screws (March 14, 2002).

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Device Classification

These devices carry an FDA product code MAI, and subsequent code HTY, and is classified as single/multiple component metallic bone fixation appliances and accessories under 21 CFR 888.3030.

Device Description

RigidFix Biocryl Cross Pin Kits

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. In accordance to CFR §888.4540, these are Class I devices and, therefore, are exempt from 510(k) premarketing notification procedures. Validated cleaning and sterilization instructions are provided for those instruments.

BioIntrafix Tibial Tapered Sheaths and Screws

The DePuy Mitek BioIntrafix Tibial Tapered Screws and BioIntrafix Tibial Sheaths are absorbable implants made from a composite of absorbable Polylactic Acid (PLA) Polymer and Tricalcium Phosphate (TCP). They are used to secure soft tissue grafts to the bone during

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	cruciate ligament reconstruction. The BioIntrafix Tibial Tapered Screws and BioIntrafix Tibial Sheaths are supplied sterile ready to use. The tie tensioner is a non-sterile, reusable instrument used to apply and measure tension on the graft. **Biocryl Interference Screws** The DePuy Mitek Biocryl Interference Screw is an absorbable, tapered, cannulated, threaded fastener for use in interference fixation of soft tissue grafts or bone-tendon grafts. The Interference Screw is made from a composite made of absorbable Poly Lactic Acid (PLA) polymer and Tricalcium Phosphate (TCP). The Biocryl Interference Screw is packaged one per pouch.
Indications for Use	**RigidFix Biocryl Cross Pin Kits** 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). **BioIntrafix Tibial Tapered Sheaths and Screws** The **BioIntrafix Tibial Screw and Tibial Sheath** are intended for fixation of soft tissue grafts during cruciate ligament reconstruction. **Biocryl Interference Screws** The **Biocryl Interference Screw** is indicated for the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee.
Safety and Performance	This premarket notification is submitted to have the protocol of the 36-month stability study reviewed to support a 3-year shelf life claim on the proposed products (i.e. RigidFix Biocryl Cross Pin Kits, BioIntrafix Tibial Tapered Sheaths and Screws, and Biocryl Interference Screws). No other changes have been made to the predicate devices. The proposed products have the same indication statements and the same technological characteristics (e.g., design, materials, etc.) as that of the respective predicate products. In addition, the descriptive characteristics are precise enough to establish substantial equivalence

between the proposed products and their respective predicates. Therefore, additional safety and performance testing on the proposed products are not necessary.

Results of performance and safety testing have been submitted in the predicate 510(k)'s (i.e. K090669 for RigidFix Biocryl Cross Pin Kits, K032167 for BioIntrafix Tibial Sheaths and Screws, and K013572 for Biocryl Interference Screws) and have demonstrated that the devices are suitable for their intended use.

Based on the identical indications for use and technological characteristics as compared to the predicate devices, the proposed RigidFix Biocryl Cross Pin Kits, BioIntrafix Tibial Sheaths and Screws, and Biocryl Interference Screws have shown to be substantially equivalent to their respective predicate devices under the Federal Food, Drug and Cosmetic Act.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Silver Spring, MD 20993-0002

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Regulatory Affairs Specialist
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Raynham, Massachusetts 02767

AUG 07 2009

Re: K091041
Trade/Device Name: RigidFix Biocryl Cross Pin Kits, BioIntrafix Tibial Tapered Sheaths and Screws, Biocryl Interference Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI, HTY, HWC
Dated: July 15, 2009
Received: July 16, 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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091041

Indications for Use

510(k) Number (if known):

Device Name: RigidFix Biocryl Cross Pin Kits
BioIntrafix Tibial Tapered Sheaths and Screws
Biocryl Interference Screws

Indications for Use:

RigidFix Biocryl Cross Pin Kits

The **RigidFix Biocryl 2.7 mm BTB Cross Pin Kit** is intended 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).

BioIntrafix Tibial Tapered Sheaths and Screws

The **BioIntrafix Tibial Screw and Tibial Sheath** are intended for fixation of soft tissue grafts during cruciate ligament reconstruction.

Biocryl Interference Screws

The **Biocryl Interference Screw** is indicated for the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee.

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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)