K112417
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DePuy Mitek Inc. never stop moving

PRODUCT: GII™ ANCHOR
SUBMISSION DATE: AUGUST 22ND, 2011
SUBMISSION TYPE: TRADITIONAL

JAN 13 2012

## ATTACHMENT 1

# 510(k) SUMMARY - DePuy Mitek GII™ ANCHOR

## SUBMITTER'S NAME AND ADDRESS

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

## CONTACT PERSON

Deep Pal
Senior Regulatory Affairs Specialist
DePuy Mitek, Inc.
*a Johnson & Johnson company*
325 Paramount Drive
Raynham, MA 02767

| | |
|---|---|
| **TELEPHONE** | 508-828-3359 |
| **FACSIMILE** | 508-977-6911 |
| **E-MAIL** | dpal3@its.jnj.com |
| **DATE PREPARED** | August 22nd, 2011 |


## NAME OF MEDICAL DEVICE

**COMMON NAME**

Bone Anchors, Screws

**TRADE NAME/PROPRIETARY NAME**

- GII™ Anchor

## SUBSTANTIAL EQUIVALENCE

There are no changes being made to the indications, product designs, material, packaging, and to the manufacturing processes. The only proposition of this 510(k) submission is to add a generic "MR-Conditional" statement and symbol to the product package insert and labels.

- **K915889** - *GII™ Anchor*
- **K111631** - *Various Metal Implants*

## DEVICE CLASSIFICATION

- **GII™ Anchor - K915889**
  - Device Classification: II
  - Device Classification Name: Fastener, Fixation, Nondegradable, Soft tissue
    Staple, Fixation, Bone
  - Regulation Number: 888.3040-Smooth or threaded metallic bone fixation fastener
    888.3030-Single/multiple component metallic bone fixation appliances and accessories
  - Classification Product Code: MBI, JDR

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## ATTACHMENT 1

*Continues...*

# 510(k) SUMMARY - DePuy Mitek MRI STATEMENT FOR METAL IMPLANTS

## INDICATIONS FOR USE

- **GII Anchors**

**SHOULDER**: Acromio-clavicular; Bankart repair; Biceps tenodesis; Capsule shift/capsulolabral reconstruction; Deltoid repair; Rotator cuff repair; SLAP lesion repair.
**ANKLE**: Achilles tendon repair/reconstruction; Lateral instability; Medial instability; Midfoot reconstructions.
**FOOT**: Hallux valgus reconstruction.
**WRIST**: Scapholunate ligament reconstruction.
**HAND**: Ulnar or lateral collateral ligament reconstruction.
**ELBOW**: Biceps tendon reattachment; Tennis elbow repair.
**KNEE**: Extra capsular reconstruction, ITB tenodesis; Lateral collateral ligament; Patellar ligament and tendon avulsion repairs; Posterior oblique ligament or joint capsule to tibia; Joint capsule closure to anterior proximal tibia; Medial collateral ligament.
**BNS**: Fixation in pubic bone for bladder neck suspension using USP #2 Class I nonabsorbable synthetic suture (e.g. polypropylene). A minimum of 2 Anchors should be used in this procedure.

## TECHNOLOGICAL CHARACTERSTICS

The only proposition of this 510(k) submission is to add a "MR-Conditional" statement and symbol to all applicable product package-insert and labels of GII™ Anchor devices. Technological characteristics including indications, product design, material, and packaging are the same as the predicate devices.

## NONCLINICAL TESTING

MRI Testing using a scanner operating with a static magnetic field was performed on the DePuy Mitek metal implant devices. The test performed, included magnetic field interaction, MRI-related heating, and the presence of artifacts at 3.0 Tesla.

## SAFETY AND PERFORMANCE

Results of "Evaluation of Magnetic Field Interactions, Heating, and Artifacts" have demonstrated that the currently marketed DePuy Mitek GII™ Anchors are "MR-conditional".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Deep Pal
Regulatory Affairs Specialist II
DePuy Mitek Inc., a johnson and johnson company
325 Paramount Drive
RAYNHAM MA 02767

JAN 13 2012

Re: K112417
Trade/Device Name: GII™ Anchor
Regulation Number: 21 CFR§ 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: January 11, 2012
Received: January 12, 2012

Dear Mr. Pal:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DePuy Mitek Inc. never stop moving

**PRODUCT:** GII™ ANCHOR
**SUBMISSION DATE:** AUGUST 22ND, 2011
**SUBMISSION TYPE:** TRADITIONAL

## ATTACHMENT 2

## INDICATIONS FOR USE FORMS

**510(k) Number (if known):** K112417

**Device Names:** GII™ Anchor

**Indications for Use:**

**SHOULDER:** Acromio-clavicular; Bankart repair; Biceps tenodesis; Capsule shift/capsulolabral reconstruction; Deltoid repair; Rotator cuff repair; SLAP lesion repair.

**ANKLE:** Achilles tendon repair/reconstruction; Lateral instability; Medial instability; Midfoot reconstructions.

**FOOT:** Hallux valgus reconstruction.

**WRIST:** Scapholunate ligament reconstruction.

**HAND:** Ulnar or lateral collateral ligament reconstruction.

**ELBOW:** Biceps tendon reattachment; Tennis elbow repair.

**KNEE:** Extra capsular reconstruction, ITB tenodesis; Lateral collateral ligament; Patellar ligament and tendon avulsion repairs; Posterior oblique ligament or joint capsule to tibia; Joint capsule closure to anterior proximal tibia; Medial collateral ligament.

**BNS:** Fixation in pubic bone for bladder neck suspension using USP #2 Class I nonabsorbable synthetic suture (e.g. polypropylene). A minimum of 2 Anchors should be used in this procedure.

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)



(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112417