K111631

DePuy Mitek Inc. never stop moving™
a Johnson & Johnson company

PRODUCT: MRI STATEMENT FOR METAL IMPLANTS
SUBMISSION DATE: JUNE 06TH, 2011
SUBMISSION TYPE: TRADITIONAL

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

SUBMITTER'S NAME AND ADDRESS

JUL 22 2011

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

CONTACT PERSON

Deep Pal
Regulatory Affairs Specialist
DePuy Mitek, Inc.
a Johnson & Johnson company
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E-MAIL	dpal3@its.jnj.com
DATE PREPARED	June 06th, 2011

NAME OF MEDICAL DEVICE

COMMON NAME

Bone Anchors, Screws

TRADE NAME/PROPRIETARY NAME

- GII Anchor/GII Quick Anchor Plus
- Healix Ti Dual Threaded Suture Anchor
- Rotator Cuff Anchor/Rotator Cuff Quick Anchor Plus
- Super Anchor/Super Quick Anchor Plus

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 inserts and labels.

- **K915889, K051989** - *GII Anchor/GII Quick Anchor Plus*
- **K082282** - *Healix Ti Dual Threaded Suture Anchor*
- **K992611, K052630** - *Rotator Cuff Anchor/Rotator Cuff Quick Anchor Plus*
- **K930893, K052631** - *Super Anchors/Super Quick Anchor Plus*

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DEVICE CLASSIFICATION

- **GII Anchor/GII Quick Anchor Plus - K915889, K051989**
  - 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

- **Healix Ti Dual Threaded Suture Anchor - K082282**
  - Device Classification: II
  - Device Classification Name: Screw, Fixation, Bone
  - Regulation Number: 888.3040-Smooth or threaded metallic bone fixation fastener
  - Classification Product Code: HWC
  - Subsequent Product Code: JDR, MBI

- **Rotator Cuff Anchor/Rotator Cuff Quick Anchor Plus - K992611, K052630**
  - Device Classification: II
  - Device Classification Name: Screw, Fixation, Bone
  - Regulation Number: 888.3040-Smooth or threaded metallic bone fixation fastener
  - Classification Product Code: HWC

- **Super Anchor/Super Quick Anchor Plus - K930893, K052631**
  - Device Classification: II
  - Device Classification Name: Staple, Fixation, Bone
  - Regulation Number: 888.3030-Single/multiple component metallic bone fixation appliances and accessories
  - Classification Product Code: JDR
  - Subsequent Product Code: JDR, MAI

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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.

- **GII Quick Anchor Plus**

The DePuy Mitek GII Anchor (QUICKANCHOR) is intended for fixation of USP size #2 suture to bone for the indications listed below.
Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsulo-labral reconstruction, biceps tenodesis, deltoid repair.
Ankle: Lateral instability, medial instability, achilles tendon repair/reconstruction, midfoot reconstruction.
Foot: Hallux valgus reconstruction.
Wrist: Scapholunate ligament.
Hand: Ulnar or lateral collateral ligament reconstruction.
Elbow: Tennis elbow repair, biceps tendon reattachment.
Knee: Extra capsular repairs; reattachment of: medial collateral ligament, lateral collateral ligament, posterior oblique ligament or joint capsule to tibia and joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions.

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

INDICATIONS FOR USE

- **Healix Ti Dual Threaded Suture Anchor**

The HEALIX Ti Dual Threaded Suture Anchor is intended for:
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular
Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament
Repair, Iliotibial Band Tenodesis, Patellar Tendon repair and secondary fixation in ACL/PCL reconstruction repair.
Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.
Hip: Capsular repair, acetabular labral repair.

- **Rotator Cuff Anchors**

(I) SHOULDER
1. Rotator Cuff

- **Rotator Cuff Quick Anchor Plus**

The DePuy Mitek RC QUICKANCHOR Anchor Plus is intended for fixation of USP size #2 suture to bone for the indications listed below.
Shoulder: Rotator cuff repair.

- **Super Anchors**

(I) SHOULDER
1. Biceps tenodesis
2. Capsule shift/capsulolabral reconstruction
3. Deltoid repair
4. Rotator cuff

(II) ANKLE
1. Achilles tendon repair/reconstruction

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

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510(k) SUMMARY - DePuy Mitek METAL IMPLANTS

INDICATIONS FOR USE

- **Super Quick Anchor Plus**

  The DePuy Mitek Super QUICKANCHOR Plus is intended for fixation of USP size #2 through #5 suture to bone for the indications listed below.

  Shoulder: Rotator cuff repair; capsular repair; biceps repair; deltoid repair.

  Ankle: Achilles tendon repair/reconstruction.

  Knee: Extra capsular repairs; reattachment of: medial collateral ligament, lateral collateral ligament, posterior oblique ligament or joint capsule to tibia and joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions.

TECHNOLOGICAL CHARACTERSTICS

The only proposition of this 510(k) submission is to add a "MR-Conditional" statement and symbol to all applicable product package-inserts and labels. 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 metal implants 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

DePuy Mitek, A Johnson & johnson Company
% Mr. Deep Pal
Regulatory Affairs Specialist II
325 Paramount Drive
Raynham, Massachusetts 02767

JUL 22 2011

Re: K111631
Trade/Device Name: Super QUICKANCHOR® Plus
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 6, 2011
Received: June 13, 2011

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,

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

Enclosure

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SUBMISSION DATE: JUNE 06TH, 2011
SUBMISSION TYPE: TRADITIONAL

INDICATIONS FOR USE FORMS

510(k) Number (if known): K111631

Device Names: Super QUICKANCHOR® Plus

Indications for Use:

The DePuy Mitek Super QUICKANCHOR Plus is intended for fixation of USP size #2 through #5 suture to bone for the indications listed below.

Shoulder: Rotator cuff repair; capsular repair; biceps repair; deltoid repair.

Ankle: Achilles tendon repair/reconstruction.

Knee: Extra capsular repairs; reattachment of: medial collateral ligament, lateral collateral ligament, posterior oblique ligament or joint capsule to tibia and joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions.

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)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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SUBMISSION DATE: JUNE 06TH, 2011
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INDICATIONS FOR USE FORMS

510(k) Number (if known): K111631

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.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

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Division of Surgical, Orthopedic,
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SUBMISSION DATE: JUNE 06TH, 2011
SUBMISSION TYPE: TRADITIONAL

INDICATIONS FOR USE FORMS

510(k) Number (if known): K111631

Device Names: GII™ QUICKANCHOR® Plus

Indications for Use:

The DePuy Mitek GII Anchor (QUICKANCHOR) is intended for fixation of USP size #2 suture to bone for the indications listed below.

Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsulo-labral reconstruction, biceps tenodesis, deltoid repair.

Ankle: Lateral instability, medial instability, achilles tendon repair/reconstruction, midfoot reconstruction.

Foot: Hallux valgus reconstruction.

Wrist: Scapholunate ligament.

Hand: Ulnar or lateral collateral ligament reconstruction.

Elbow: Tennis elbow repair, biceps tendon reattachment.

Knee: Extra capsular repairs; reattachment of: medial collateral ligament, lateral collateral ligament, posterior oblique ligament or joint capsule to tibia and joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. McKerson

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PRODUCT: MRI STATEMENT FOR METAL IMPLANTS
SUBMISSION DATE: JUNE 06TH, 2011
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INDICATIONS FOR USE FORMS

510(k) Number (if known): K111631

Device Names: HEALIX Ti™ Dual Threaded Suture Anchor

Indications for Use:

The HEALIX Ti Dual Threaded Suture Anchor is intended for:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Patellar Tendon repair and secondary fixation in ACL/PCL reconstruction repair.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hip: Capsular repair, acetabular labral repair.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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INDICATIONS FOR USE FORMS

510(k) Number (if known): K111631

Device Names: ROTATOR CUFF ANCHOR

Indications for Use:

(I) SHOULDER
1. Rotator Cuff

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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for M. Melkerson
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Division of Surgical, Orthopedic,
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INDICATIONS FOR USE FORMS

510(k) Number (if known): K111631

Device Names: Rotator Cuff QUICKANCHOR® Plus

Indications for Use:

The DePuy Mitek RC QUICKANCHOR Anchor Plus is intended for fixation of USP size #2 suture to bone for the indications listed below.

Shoulder: Rotator cuff repair.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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INDICATIONS FOR USE FORMS

510(k) Number (if known): K111631

Device Names: DePuy MITEK SUPERANCHOR

Indications for Use:

(I) SHOULDER
1. Biceps tenodesis
2. Capsule shift/capsulolabral reconstruction
3. Deltoid repair
4. Rotator cuff

(II) ANKLE
1. Achilles tendon repair/reconstruction

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

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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for M. Welkom

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Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111631