MAY 2 8 2004

Pg 1 of 2

K041115

510(k) Summary – GII QuickAnchor Plus

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062
Contact Person	Allyson Barford Regulatory Affairs Associate DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062 Telephone: 781-251-2794 Facsimile: 781-278-9578 e-mail: abarford@dpyus.jnj.com
Name of Medical Device	Device Regulation: Staple, Fixation, Bone (21 CFR 888.3030) Product code: MBI Common/Usual Name: Staple, Fixation, Bone Proprietary Name: GII QuickAnchor Plus
Device Classification	Staple, Fixation, Bone devices have been classified as Class II, MBI according to 21 CFR 888.3030. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Staple, Fixation, Bone devices.
Indications for Use	The 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.
Device Description	The GII QuickAnchor Plus is intended as an upgrade of the current GII Anchor. While retaining the current GII Anchor design, the new system includes enhanced ergonomics, and improved visualization. The product will be offered with both Ethibond and Panacryl suture. The ergonomics are improved by allowing a single-handed operation. In addition, the visualization of the anchor is improved by increasing the length of the inserter shafts. The GII Anchor is a metallic (6Al-4V ELI Titanium base and NiTi Titanium Alloy arcs) and is used to assist in the reattachment of soft tissue to bone. The anchor is identical to the currently marketed Mitek GII Anchor (K915889).
Substantial Equivalence	Based on the type of changes being made and the fact that the GII QuickAnchor Plus represents the same fundamental scientific technology as the existing GII Anchor; Mitek believes the GII QuickAnchor Plus is substantially equivalent to Mitek's existing GII Anchor (K915889).
Safety	Biocompatibility studies have demonstrated the GII QuickAnchor Plus to be non-toxic, non-irritating, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2004

Allyson Barford
Regulatory Affairs Associate
Depuy Mitek
a Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K041115
Trade/Device Name: GII QuickAnchor Plus
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR
Dated: April 6, 2004
Received: April 29, 2004

Dear Ms Barford:

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.

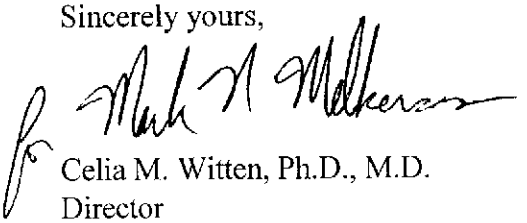
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
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): K041115

Device Names:

GII QuickAnchor Plus

Indications for Use:

The 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.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use _____

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041115