

SECTION 2 – 510(k) SUMMARY

FEB - 4 2010

OMNISPAN Meniscal Repair System

Submitter's Name and Address:

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

Contact Person

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Name of Medical Device

Classification Name: Smooth or threaded metallic bone fixation fastener
Common/Usual Name: Bone Fixation Fastener
Proprietary Name: OMNISPAN Meniscal Repair System

Device Classification

This device carries FDA product codes MBI, NEW and GAT, and is classified as Smooth or threaded metallic bone fixation fastener under 21 CFR 888.3040.

Device Description

The proposed **OMNISPAN Meniscal Repair System** consists of two sterile PEEK (polyetheretherketone) implants connected by a sliding loop and fixed leg of absorbable size #2-0 Orthocord suture, a sterile, disposable Deployment Gun with malleable Graft Retractor. The implants together with the suture provide compression across the tear in the meniscus.

Indications for Use

The proposed **OMNISPAN Meniscal Repair System** is intended for use in the arthroscopic fixation of soft tissue procedures such as meniscal repair.

Substantial Equivalence

The proposed **OMNISPAN Meniscal Repair System** is substantially equivalent to:

- K002406 Mitek Rapidloc Meniscal Repair Device (February 15, 2001);
- K023388 Mitek PDS Rapidloc Meniscal Repair Device (December 27, 2002).

The size #2-0 Orthocord suture provided with the proposed **OMNISPAN Meniscal Repair System** is identical to the size #2-0 Orthocord in:

- K071257 Mini Quickanchor and Quickanchor Plus with Size #2-0 Orthocord (June 29, 2007);
- K080918 Double Armed Meniscal Needles with Size #2-0 Orthocord (April 23, 2008).

The proposed **OMNISPAN Meniscal Repair System** is also similar to:

- K072322 Smith & Nephew Ultra Fast-Fix Device (September 18, 2007);
- K073149 Arthrex Meniscal Cinch (February 11, 2008).

Safety and Performance

Results of performance and safety testing have demonstrated that the modified device is suitable for its intended use.

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed **OMNISPAN Meniscal Repair System** has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Depuy Mitek
c/o Ms. Ruth Forstadt
Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

FEB - 4 2010

Re: K092836
Trade/Device Name: OMNISPAN Meniscal Repair System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, NEW, GAT
Dated: January 29, 2010
Received: February 1, 2010

Dear Ms. Forstadt:

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

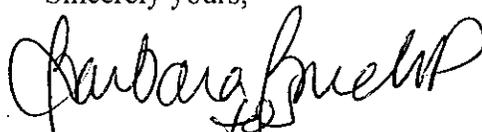
Page 2 – Ms. Ruth Forstadt

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

Indications for Use

510(k) Number (if known): K092836

Device Name: OMNISPAN Meniscal Repair System

Indications for Use:

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Prescription Use x
(Part 21 CFR 801 Subpart D)

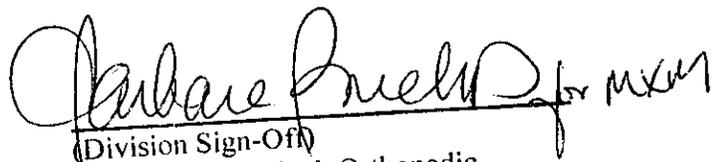
AND/OR

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)

Page 1 of 1


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

510(k) Number K092836