K122869(1/2)

DEC 13 2012

ATTACHMENT 1

510(k) SUMMARY - DEPUY MITEK MILAGRO® INTERFERENCE SCREWS

SUBMITTER'S NAME AND ADDRESS

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

CONTACT PERSON

Kristine Christo
DePuy Mitek Regulatory Affairs

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E-MAIL	KChristo@its.jnj.com
DATE PREPARED	September 18th, 2012

NAME OF MEDICAL DEVICE

CLASSIFICATION NAME

Fastener, Fixation, Biodegradable, Soft Tissue

COMMON/USUAL NAME

Bone Anchor

PROPRIETARY NAME

DePuy Mitek Milagro® Interference Screws

SUBSTANTIAL EQUIVALENCE

The proposed 6, 7 and 8 x15mm DePuy Mitek Milagro® Interference Screws are substantially equivalent to the following devices.

- K120589, K103831, K060830, K032717: Milagro Interference Screws
- K051726, K041356, K020043: Arthrex Tenodesis Screws

FDA PRODUCT CODE

MAI, HWC

DEVICE CLASSIFICATION

This type of **fixation screw** was originally classified as a **Class II** medical device by the **Orthopedic Review Panel,** regulated as 21 CFR 888.3040 Smooth or Threaded Metallic Bone Fixation Fastener.

ATTACHMENT 1

Continues...

510(k) SUMMARY - DEPUY MITEK MILAGRO® INTERFERENCE SCREWS

DEVICE DESCRIPTION

The DePuy Mitek Milagro® Interference Screws are absorbable, tapered, cannulated, threaded fasteners 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 *(lactide-co-glycolide)* polymer and Tricalcium Phosphate (TCP).

Modular Drivers, Ratchet Handle, Guidewires, a Tap and Notcher are provided separately as reusable accessories to assist in the placement of the MILAGRO BR Screw.

The proposed DePuy Mitek Milagro® Interference Screws are offered in diameters of 5, 6mm and in the length of 12mm.

INDICATIONS FOR USE

The DePuy Mitek MILAGRO BR Interference Screws are designed to attach soft tissues to bone in orthopedic surgical procedures for following indications:
Shoulder: Proximal Biceps Tenodesis, Acromio-Clavicular Repair
Elbow: Distal Biceps Tenodesis, Ulnar Collateral Ligament repair
Knee: Collateral Ligament Repair

TECHNOLOGICAL CHARACTERSTICS

The design specifications of the proposed DePuy Mitek Milagro® Interference Screws are substantially equivalent to the existing DePuy Mitek Milagro® Interference Screws cleared under 510(k) K120589, K103831, K060830 and K032717 except that the proposed DePuy Mitek Milagro® Interference Screws are smaller in size. Technological characteristics including design construct, and indications are similar to the predicate devices. There have been no changes to the material used to manufacture the product, packaging, and or to the sterilization processes, sterilization contractors; these are identical to that used for the currently marketed DePuy Mitek Milagro® Interference Screw *(previously cleared by the FDA under the premarket notification K032717, K060830, K103831 and K120589).*

NONCLINICAL TESTING

Product Design Verification activities, such as, Insertion Torque, Anchor Pullout (at T=0, 3, 6 and 12 week in-vitro physiological aging), and Torque to Failure were performed on the implant.

SAFETY AND PERFORMANCE

Results of performance and safety testing have demonstrated that the proposed device is substantially equivalent to the predicate devices.
Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed Small Size DePuy Mitek Milagro® Interference Screws have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DePuy Mitek, A Johnson & Johnson Company
% Ms. Kristine Christo
Regulatory Affairs Manager
325 Paramount Drive
Raynham, Massachusetts 02767

Letter dated: December 13, 2012

Re: K122869
Trade/Device Name: 5, 6x12mm Milagro Interference Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MAI, HWC
Dated: September 18, 2012
Received: September 19, 2012

Dear Ms. Christo:

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

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

Enclosure

DePuy never stop moving

ATTACHMENT 2

INDICATIONS FOR USE

510(k) Number (if known): K122869

Device Names: 5, 6x12mm Milagro® Interference Screws

Indications for Use:
The DePuy Mitek MILAGRO BR Interference Screws are designed to attach soft tissues to bone in orthopedic surgical procedures for following indications:
Shoulder: Proximal Biceps Tenodesis, Acromio-Clavicular Repair
Elbow: Distal Biceps Tenodesis, Ulnar Collateral Ligament repair
Knee: Collateral Ligament Repair

Prescription Use √ 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)
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Casey Hanley

For Division of Orthopaedic Devices