FEB 1 2013

SECTION 2 - 510(k) SUMMARY

MILAGRO ADVANCE Interference Screw

Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767
Contact Person	Yayoi Fujimaki Regulatory Affairs Senior Associate DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-828-3541 Facsimile: 508-977-6911 e-mail: yfujima1@its.jnj.com
Name of Medical Device	Proprietary Name: MILAGRO ADVANCE Interference Screw Classification Name: Smooth or threaded metallic bone fixation fastener Common Name: fastener, fixation, biodegradable, soft tissue
Substantial Equivalence Facility	The MILAGRO ADVANCE Interference Screw is substantially equivalent to: ▪ K060830: MILAGRO Interference Screw ▪ K032717: Biocryl Rapide Interference Screw
Device Classification	HWC - Smooth or threaded metallic bone fixation fastener, classified as Class II, regulated under 21 CFR 888.3040 MAI - Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, regulated under 21 CFR 888.3030.

Device Description	The MILAGRO ADVANCE Interference Screw is an absorbable, tapered, cannulated, threaded fastener 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). The MILAGRO ADVANCE Interference Screw is provided sterile and is for single patient use only.
Indications for Use	The MILAGRO ADVANCE Interference Screw is intended for attachment of soft tissue grafts or bone-tendon-bone grafts to the tibia and/or femur during cruciate ligament reconstruction procedures. Additionally, the 7, 8 and 9 mm x 23 mm screws will be indicated for: medial and lateral collateral ligament repair of the knee, proximal bicep tenodesis in the shoulder and distal bicep tenodesis in the elbow.
Safety and Performance	**Non-clinical Testing** Screw fixation strength testing (at time zero and *in vitro* testing throughout healing period) was performed to confirm that the proposed screws perform similarly to the predicate screws or meet the acceptance criteria. Screw torque testing was performed to confirm that there is no issue for screw insertion into the bone. Results of the testing have demonstrated that the proposed screws are suitable for the intended use. Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed MILAGRO ADVANCE Interference Screw has been shown to be substantially equivalent to the predicate device 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 20993-0002

DePuy Mitek, a Johnson and Johnson Company
% Yayoi Fujimaki
Regulatory Affairs Senior Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Letter dated: February 1, 2013

Re: K123362
Trade/Device Name: MILAGRO ADVANCE Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MAI
Dated: January 8, 2013
Received: January 11, 2013

Dear Yayoi Fujimaki:

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

Indications for Use

510(k) Number (if known): K123362

Device Name: MILAGRO ADVANCE Interference Screw

Indications for Use:

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Prescription Use ___x___ 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)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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