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

June 9, 2016

Medos International SARL
% Ms. Kristine Christo
Director, Regulatory Affairs
Depuy Mitek Inc., a Johnson & Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K161001
Trade/Device Name: MILAGRO® ADVANCE PEEK Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: Class II
Product Code: MBI
Dated: April 7, 2016
Received: April 11, 2016

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 Parts 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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 -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K161001

Device Name
MILAGRO® ADVANCE PEEK Interference Screw

Indications for Use *(Describe)*

The MILAGRO® ADVANCE PEEK 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 are indicated for: medial and lateral collateral ligament repair , medial patellofemoral ligament reconstruction (femur fixation) of the knee, proximal bicep tenodesis in the shoulder and distal bicep tenodesis in the elbow.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 2 - 510(k) SUMMARY

MILAGRO® ADVANCE PEEK Interference Screw

Submitter's Name and Address	DePuy Mitek a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767 Date Prepared: March 25, 2016
Contact Person	Kristine Christo Director, Regulatory Affairs DePuy Mitek, Inc. a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-828-3359 Facsimile: 508-977-6911 e-mail: kchristo@its.jnj.com
Name of Medical Device	Proprietary Name: MILAGRO® ADVANCE PEEK Interference Screw Classification Name: Smooth or threaded metallic bone fixation fasteners Common Name: Fastener, fixation, nondegradable, soft tissue
Substantial Equivalence	The MILAGRO® ADVANCE PEEK Interference Screw is substantially equivalent to: ▪ K123362, K143660, MILAGRO ADVANCE™ Interference Screw Reference device: ▪ K130539 Healix Advance™ Knotless PEEK Anchor
Device Classification	Smooth or threaded metallic bone fixation fastener, classified as Class II, product code MBI, regulated under 21 CFR 888.3040.
Device Description	The MILAGRO® ADVANCE PEEK Interference Screw is a non-absorbable, tapered, cannulated, threaded fastener for use in interference fixation of soft tissue grafts or bone-tendon-bone grafts. The Interference Screw is made from Polyetheretherkeytone (PEEK). The MILAGRO® ADVANCE PEEK Interference Screw is provided sterile and is for single patient use only.

Technological Characteristics	The proposed MILAGRO® ADVANCE PEEK Interference Screw is similar to the predicate MILAGRO ADVANCE™ Interference Screw (K123362, K143660) in that they share the same indication for use, screw design, sterilization method, and shelf life. The proposed MILAGRO® ADVANCE PEEK Interference Screw is similar to the reference device, Healix Advance™ Knotless PEEK Anchor (K130539), in that they share the same PEEK material.
Indications for Use	The MILAGRO® ADVANCE PEEK 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, medial patellofemoral ligament reconstruction (femur fixation) of the knee, proximal bicep tenodesis in the shoulder and distal bicep tenodesis in the elbow.
Non clinical Testing	Verification activities were performed on the implant and / or its predicate. Testing assessments include pull out testing, and insertion / failure torque.
Safety and Performance	Results of performance testing have demonstrated that the proposed devices are suitable for their intended use. The proposed device also met requirement of bacterial endotoxin testing. Based on similarities in the indications for use, technological characteristics, and performance in comparison to the predicate devices, the proposed MILAGRO® ADVANCE PEEK Interference Screw has shown to be substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.