DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 21, 2015

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

Re: K143660
Trade/Device Name: Milagro / Milagro Advance Interference Screw
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: April 20, 2015
Received: April 22, 2015

Dear Ms. 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 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,

Lori A. Wiggins -S

for
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 below.

510(k) Number *(if known)*

K143660

Device Name
Milagro / Milagro Advance Interference Screw

Indications for Use *(Describe)*

Milagro Interference Screw (5x12, 6x12, 7x15, 8x15)
The MILAGRO BR Interference Screws are designed to attach soft tissues to bone in Orthopedic surgical procedures for the following indications:
Shoulder: Proximal Biceps Tenodesis, Acromio-Clavicular Repair
Elbow: Distal Biceps Tenodesis, Ulnar Collateral Ligament Repair
Knee: Collateral Ligament Repair, Medial Patellofemoral Ligament Reconstruction (patella fixation)

Milagro Advance Interference Screw (7x23, 8x23, 9x23)
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 9mm x 23mm 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.

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510(k) SUMMARY
Milagro / Milagro Advance Interference Screw

I. SUBMITTER

Date Prepared	December 18, 2014	
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 *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

II. DEVICE

Name of Device	▪ Milagro Interference Screw (K122869, K120589) ▪ Milagro Advance Interference Screw (K123362)
Common Name	fastener, fixation, biodegradable, soft tissue
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	Class II
Product Code	MAI (21CFR888.3030)

III. PREDICATE DEVICE

Predicate Device	▪ Bioraptor Knotless Anchor (K121018, K093428; Smith & Nephew)
Reference Device	▪ BioTenodesis Interference Screw (K051726, K041356, K020043; Arthrex)

IV. DEVICE DESCRIPTION

Device Description	The proposed devices are interference screws used for attachment of soft tissue to bone in Orthopedic surgeries. The proposed devices are cannulated, threaded interference screws, made of absorbable Biocryl® Rapide™ (composite of β-TCP and PLGA copolymer). The devices are provided as sterile (EtO), and are for

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	single patient use only. There is no accessory accompanied with the devices. Manual Orthopedic instruments such as tap and driver are used for screw insertion. Instruments are classified as LXH: Orthopedic Manual Surgical Instruments, Class I Exempt device, regulated per 21 CFR 888.4540. No new instrumentation is developed for the purpose of this submission.

V. INDICATIONS FOR USE

Milagro Interference Screw (5x12, 6x12, 7x15, 8x15)	The 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, Medial Patellofemoral Ligament Reconstruction (patella fixation)
Milagro Advance Interference Screw (7x23, 8x23, 9x23)	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 9mm x 23mm 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Same technological elements	▪ Indication: The proposed indication is Medial Patellofemoral Ligament Reconstruction that is a part of Patellar Realignment for which is the predicate device is indicated. The reference is used for the same intended use (soft tissue fixation to bone) and used by similar orthopedic procedures. ▪ Implant design: The proposed and predicate devices are cannulated, threaded/ribbed bone implants used for soft tissue fixation to bone. This is similar to the predicate and reference. ▪ Implant size: Within the size range of the predicate and reference. ▪ Material: The proposed devices are absorbable. The reference is also absorbable, and used for the same intended use (soft tissue fixation to bone). Material degradation did not raise a performance concern per bench-top fixation strength testing.
Different technological elements	There is no significant different technological element.

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VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Bench-top mechanical testing	Fixation strength data on bone foam model were compared with the data of the predicate device. The data demonstrated substantial equivalence of fixation performance.
Summary	The fixation strength testing demonstrated substantial equivalency of product performance. There is no change to material, packaging system and sterilization; therefore additional studies of biocompatibility, sterility and stability were unnecessary.

VIII. CONCLUSION

Substantial Equivalence	The proposed devices are, similarly to the predicate and reference devices, bone implants that are intended to be used for stabilizing soft tissue to bone in such as knee, shoulder and elbow. The proposed devices are similar to the predicate and reference devices in technological elements. The proposed devices demonstrated substantial equivalency of device performance (bench-top). Regarding to the proposed devices, there has been no change to material, design, sterilization and manufacturing; therefore there is no change to material safety, stability and sterility to the proposed devices. In conclusion, there is no significant difference between the proposed devices and the predicate/reference devices, and there is no new question raised regarding to product safety and efficacy. The proposed devices are considered substantially equivalent to the predicate device.