March 15, 2024

DePuy Mitek
Ashley Aromando
Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K240441
Trade/Device Name: MILAGRO Interference Screw; 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, MBI
Dated: February 13, 2024
Received: February 14, 2024

Dear Ashley Aromando:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sara S. Thompson -S

For

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240441

Device Name
MILAGRO ADVANCE PEEK Interference Screw

Indications for Use *(Describe)*
MILAGRO ADVANCE PEEK Interference Screws (7x23mm, 8x23mm, 9x23mm):

The DePuy Mitek MILAGRO ADVANCE PEEK Interference Screw is indicated as follows:
• Knee: Attachment of a bone-tendon-bone (BTB) graft to the tibia and/or femur during cruciate ligament reconstruction procedures.
• Knee: Attachment of a soft tissue (ST) graft to the tibia and/or femur during cruciate ligament reconstruction
• Knee: Medial and lateral collateral ligament repair
• Knee: Medial patellofemoral ligament reconstruction (femur fixation)
• Shoulder: Proximal Biceps Tenodesis
• Elbow: Distal Biceps Tenodesis
• Foot and Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-Foot Reconstruction, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240441

Device Name
MILAGRO ADVANCE PEEK Interference Screw

Indications for Use *(Describe)*
MILAGRO ADVANCE PEEK Interference Screws (7x30mm, 8x30mm):

The DePuy Mitek MILAGRO ADVANCE PEEK Interference Screw is indicated as follows:

• Knee: Attachment of a bone-tendon-bone (BTB) graft to the tibia and/or femur during cruciate ligament reconstruction procedures.
• Knee: Attachment of a soft tissue (ST) graft to the tibia and/or femur during cruciate ligament reconstruction
• Foot and Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-Foot Reconstruction, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

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

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K240441

Device Name
MILAGRO ADVANCE BR Interference Screw

Indications for Use *(Describe)*
MILAGRO ADVANCE BR Interference Screws (7x23mm, 8x23mm, 9x23mm):

The DePuy Mitek MILAGRO ADVANCE BR Interference Screw is indicated as follows:
• Knee: Attachment of a bone-tendon-bone (BTB) graft to the tibia and/or femur during cruciate ligament reconstruction procedures.
• Knee: Attachment of a soft tissue (ST) graft to the tibia and/or femur during cruciate ligament reconstruction
• Knee: Medial and lateral collateral ligament repair, medial patellofemoral ligament reconstruction (femur fixation)
• Shoulder: Proximal Biceps Tenodesis
• Elbow: Distal Biceps Tenodesis
• Foot and Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-Foot Reconstruction, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

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)

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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240441

Device Name
MILAGRO ADVANCE BR Interference Screw

Indications for Use *(Describe)*
MILAGRO ADVANCE BR Interference Screws (8x30mm, 7x30mm):

The DePuy Mitek MILAGRO ADVANCE BR Interference Screw is indicated as follows:
• Knee: Attachment of a bone-tendon-bone (BTB) graft to the tibia and/or femur during cruciate ligament reconstruction procedures.
• Knee: Attachment of a soft tissue (ST) graft to the tibia and/or femur during cruciate ligament reconstruction
• Foot and Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-Foot Reconstruction, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

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)

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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240441

Device Name
MILAGRO BR Interference Screw

Indications for Use *(Describe)*
MILAGRO BR Interference Screws (7x15mm, 6x12mm, 5x12mm):

The DePuy Mitek MILAGRO BR Interference Screws 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)
- Foot and Ankle: Lateral Stabilization, Medial Stabilization, Mid-Foot Reconstruction, Tendon Transfer in the Foot and Ankle

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240441

Device Name
MILAGRO BR Interference Screw

Indications for Use *(Describe)*
MILAGRO BR Interference Screws (5x23mm, 5x30mm, 6x23mm, 6x30mm):

The DePuy Mitek MILAGRO Interference Screw is indicated as follows:

• Knee: (ST) graft to the tibia and/or femur during cruciate ligament reconstruction procedures
• Knee: Medial and lateral collateral ligament repair*
• Shoulder: Proximal bicep tenodesis*
• Elbow: Distal bicep tenodesis*
• Foot and Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-Foot Reconstruction, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

* These indications do not apply to 5x30mm Screws and 6x30mm Screws

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)

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510(k) Summary

MILAGRO Interference Screw, MILAGRO ADVANCE Interference Screws

Date Prepared: 02/13/2024

Submitter's Name and Address

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

On behalf of:
Medos International SARL
Chemin-Blanc 38, Le Locle Neuchatel
CH 2400, Switzerland

Contact Person

Ashley Aromando
Manager, Regulatory Affairs

Telephone: 508-977-3907
Email: aaromand@its.jnj.com

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

Name of Medical Device

Proprietary Name:
MILAGRO Interference Screw,
MILAGRO ADVANCE Interference Screw

Classification Name:
Fastener, Fixation, Biodegradable, Soft Tissue; Fastener, Fixation, Nondegradable, Soft Tissue

Product Code:
MAI, MBI

Common Name:
Screw, Fixation, Bone

Substantial Equivalence

The MILAGRO Interference Screws (23mm, 30mm lengths) are substantially equivalent to predicate:

- K103831 MILAGRO Interference Screws

The MILAGRO Interference Screws (12mm, 15mm lengths) and MILAGRO ADVANCE BR Interference Screws (23mm lengths) are substantially equivalent to predicate:

	• K143660 MILAGRO, MILAGRO ADVANCE Interference Screws The MILAGRO ADVANCE BR Screws (30mm lengths) are substantially equivalent to predicate: • K123362 MILAGRO ADVANCE Interference Screws The MILAGRO ADVANCE PEEK Screws are substantially equivalent to predicate: • K161001 MILAGRO ADVANCE PEEK Interference Screws
Device Classification	The MILGRO and MILAGRO ADVANCE Interference Screws are classified as: Single/multiple component metallic bone fixation appliances and accessories classified as Class II, product code MAI, regulated under 21 CFR 888.3030. Smooth or threaded metallic bone fixation fastener classified as Class II, product code MBI, regulated under 21 CFR 888.3040.
Device Panel	Orthopedic Devices
Device Description	The subject devices of this Special 510(k) are the MILAGRO Interference Screws and the Milagro ADVANCE Interference Screws. These interference screws are cannulated, threaded, tapered fasteners for use in interference fixation of soft tissue grafts and/or bone-tendon-bone grafts. The MILAGRO Interference Screws and MILAGRO ADVANCE Interference Screws are offered in varying sizing configurations. The devices are offered in absorbable Biocryl Rapide material which is a biocomposite material of 70% PLGA copolymer (85% PLLA/15% PGA) and 30% β-TCP or PEEK (Polyether ether ketone) material. The devices are provided sterile via Ethylene Oxide (EO) sterilization and are for single use only.
Technological Characteristics	The anchor design, materials, principal of operation, and intended use of the subject devices are identical to that of the predicate devices. This submission is made in support of a modification to the labeling of the subject devices to add additional foot and ankle indications.
Indications for Use	<u>MILAGRO BR Interference Screws (5x23mm, 5x30mm, 6x23mm, 6x30mm):</u> The DePuy Mitek MILAGRO Interference Screw is indicated as follows:

- **Knee**: (ST) graft to the tibia and/or femur during cruciate ligament reconstruction procedures
- **Knee**: Medial and lateral collateral ligament repair*
- **Shoulder**: Proximal bicep tenodesis*
- **Elbow**: Distal bicep tenodesis*
- **Foot and Ankle**: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-Foot Reconstruction, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

* These indications do not apply to 5x30mm Screws and 6x30mm Screws

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MILAGRO BR Interference Screws (7x15mm, 6x12mm, 5x12mm):

The DePuy Mitek MILAGRO BR Interference Screws 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)
- **Foot and Ankle**: Lateral Stabilization, Medial Stabilization, Mid-Foot Reconstruction, Tendon Transfer in the Foot and Ankle

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MILAGRO ADVANCE BR Interference Screws (7x23mm, 8x23mm, 9x23mm):

The DePuy Mitek MILAGRO ADVANCE BR Interference Screw is indicated as follows:

- **Knee**: Attachment of a bone-tendon-bone (BTB) graft to the tibia and/or femur during cruciate ligament reconstruction procedures.
- **Knee**: Attachment of a soft tissue (ST) graft to the tibia and/or femur during cruciate ligament reconstruction
- **Knee**: Medial and lateral collateral ligament repair, medial patellofemoral ligament reconstruction (femur fixation)
- Shoulder: Proximal Biceps Tenodesis
- **Elbow**: Distal Biceps Tenodesis
- **Foot and Ankle**: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-Foot Reconstruction, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

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MILAGRO ADVANCE BR Interference Screws (8x30mm, 7x30mm):

The DePuy Mitek MILAGRO ADVANCE BR Interference Screw is indicated as follows:

- **Knee**: Attachment of a bone-tendon-bone (BTB) graft to the tibia and/or femur during cruciate ligament reconstruction procedures.

- **Knee**: Attachment of a soft tissue (ST) graft to the tibia and/or femur during cruciate ligament reconstruction
- **Foot and Ankle**: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-Foot Reconstruction, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

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MILAGRO ADVANCE PEEK Interference Screws (7x23mm, 8x23mm, 9x23mm):

The DePuy Mitek MILAGRO ADVANCE PEEK Interference Screw is indicated as follows:

- **Knee**: Attachment of a bone-tendon-bone (BTB) graft to the tibia and/or femur during cruciate ligament reconstruction procedures.
- **Knee**: Attachment of a soft tissue (ST) graft to the tibia and/or femur during cruciate ligament reconstruction
- **Knee**: Medial and lateral collateral ligament repair
- **Knee**: Medial patellofemoral ligament reconstruction (femur fixation)
- **Shoulder**: Proximal Biceps Tenodesis
- **Elbow**: Distal Biceps Tenodesis
- **Foot and Ankle**: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-Foot Reconstruction, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

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MILAGRO ADVANCE PEEK Interference Screws (7x30mm, 8x30mm):

The DePuy Mitek MILAGRO ADVANCE PEEK Interference Screw is indicated as follows:

- **Knee**: Attachment of a bone-tendon-bone (BTB) graft to the tibia and/or femur during cruciate ligament reconstruction procedures.
- **Knee**: Attachment of a soft tissue (ST) graft to the tibia and/or femur during cruciate ligament reconstruction
- **Foot and Ankle**: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-Foot Reconstruction, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

Non-clinical Testing	Verification activities were performed on the proposed device. Verification included an assessment of fixation strength for proposed indications at T=0 and over the healing period, as well as performance testing for insertion force.
Safety and Performance	Results of performance testing have demonstrated that the proposed devices are suitable for the additional indications for use.

Based on similarities in the intended use, technological characteristics, and performance in comparison to the predicate devices, the modified MILAGRO and MILAGRO ADVANCE Interference Screws have shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.