September 11, 2024

DePuy Mitek
Lidia Moses
Regulatory Affairs Specialist II
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K241010
Trade/Device Name: HEALIX ADVANCE Knotless anchors; HEALIX ADVANCE Self-Punching anchors
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: April 12, 2024
Received: September 9, 2024

Dear Lidia Moses:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Thomas Mcnamara -S

For: Christopher Ferreira, MS
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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K241010

Device Name

HEALIX ADVANCE Knotless anchors;
HEALIX ADVANCE Self-Punching anchors

Indications for Use *(Describe)*

HEALIX ADVANCE Knotless anchors:

The DePuy Mitek HEALIX ADVANCE Knotless BR anchors is indicated as follows:
• Shoulder: Rotator Cuff Repair
• Shoulder: Bicep Tenodesis
• Shoulder: Deltoid Repair
• Elbow: Ulnar Collateral Ligament (UCL)
• Elbow: Radial Collateral Ligament (RCL)
• Knee: Posterior Oblique
• Knee: Medial Collateral Ligament (MCL)
• Knee: Lateral Collateral Ligament (LCL)
• Knee: liotibial (IT) Band Tenodesis
• Knee: Anterior Cruciate Ligament (ACL) Repair
• Knee: Secondary Fixation in ACL/PCL Reconstruction/Repair
• Knee: Meniscal Root Repair
• Foot and Ankle: Achilles Tendon Repair

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The DePuy Mitek HEALIX ADVANCE KNOTLESS PEEK Anchors is indicated as follows:
• Shoulder: Rotator Cuff Repair
• Shoulder: Bicep Tenodesis
• Shoulder: Deltoid Repair
• Elbow: Ulnar Collateral Ligament (UCL)
• Elbow: Radial Collateral Ligament (RCL)
• Knee: Posterior Oblique
• Knee: Medial Collateral Ligament (MCL)
• Knee: Lateral Collateral Ligament (LCL)
• Knee: liotibial (IT) Band Tenodesis
• Knee: Anterior Cruciate Ligament (ACL) Repair
• Knee: Secondary Fixation in ACL/PCL Reconstruction/Repair
• Knee: Meniscal Root Repair
• Foot and Ankle: Achilles Tendon Repair
• Foot and Ankle: Lateral Stabilization
• Foot and Ankle: Medial Stabilization

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HEALIX ADVANCE Self-Punching anchors:

The DePuy Mitek HEALIX ADVANCE SP Biocomposite Anchors is indicated as follows:
• Shoulder: Rotator Cuff Repair
• Shoulder: Bicep Tenodesis

• Shoulder: Deltoid Repair
• Elbow: Ulnar Collateral Ligament (UCL)
• Elbow: Radial Collateral Ligament (RCL)
• Knee: Posterior Oblique
• Knee: Medial Collateral Ligament (MCL)
• Knee: Lateral Collateral Ligament (LCL)
• Knee: liotibial (IT) Band Tenodesis
• Knee: Anterior Cruciate Ligament (ACL) Repair
• Knee: Secondary Fixation in ACL/PCL Reconstruction/Repair
• Knee: Meniscal Root Repair

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The DePuy Mitek HEALIX ADVANCE SP PEEK Anchors is indicated as follows:
• Shoulder: Rotator Cuff Repair
• Shoulder: Bicep Tenodesis
• Shoulder: Deltoid Repair
• Elbow: Ulnar Collateral Ligament (UCL)
• Elbow: Radial Collateral Ligament (RCL)
• Knee: Posterior Oblique
• Knee: Medial Collateral Ligament (MCL)
• Knee: Lateral Collateral Ligament (LCL)
• Knee: liotibial (IT) Band Tenodesis
• Knee: Anterior Cruciate Ligament (ACL) Repair
• Knee: Secondary Fixation in ACL/PCL Reconstruction/Repair
• Knee: Meniscal Root Repair
• Foot and Ankle: Achilles Tendon Repair
• Foot and Ankle: Lateral Stabilization
• Foot and Ankle: Medial Stabilization

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.**

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

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# 510(k) Summary

**HEALIX ADVANCE™ Knotless Anchors, HEALIX ADVANCE™ Self-Punching Anchors**

**Date Prepared: 04/12/2024**

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**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

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**Contact Person**

Lidia Moses
Regulatory Affairs Specialist II, Regulatory Affairs

Telephone: 508-405-7569
Email: lmoses@its.jnj.com

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

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**Name of Medical Device**

Proprietary Name:
A) HEALIX ADVANCE™ KNOTLESS BR Anchor
B) HEALIX ADVANCE™ KNOTLESS PEEK Anchor
C) HEALIX ADVANCE™ SP BIOCOMPOSITE Anchor
D) HEALIX ADVANCE™ SP PEEK Anchor

Classification Name:
A) Single/multiple component metallic bone fixation appliances and accessories
B) Smooth or threaded metallic bone fixation fastener
C) Single/multiple component metallic bone fixation appliances and accessories
D) Smooth or threaded metallic bone fixation fastener

Product Code:
A) MAI
B) MBI
C) MAI
D) MBI

Common Name:
Suture Anchor

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| **Substantial Equivalence** | The HEALIX ADVANCE Knotless BR anchors are substantially equivalent to predicate:<br>• K180101 HEALIX ADVANCE Knotless BR<br><br>The HEALIX ADVANCE Knotless PEEK anchors are substantially equivalent to predicate:<br>• K171114 HEALIX ADVANCE Knotless PEEK<br><br>The HEALIX ADVANCE Self-Punching Biocomposite anchors (4.9mm, 5.5mm lengths) are substantially equivalent to predicate:<br>• K191242 HEALIX ADVANCE Self-Punching Biocomposite anchors (4.9mm, 5.5mm lengths)<br><br>The HEALIX ADVANCE Self-Punching PEEK anchors (4.9mm, 5.5mm lengths) are substantially equivalent to predicate:<br>• K182941 HEALIX ADVANCE Self-Punching PEEK anchors (4.9mm, 5.5mm lengths)<br><br>The HEALIX ADVANCE Self-Punching PEEK & Biocomposite anchors 6.5mm lengths) are substantially equivalent to predicate:<br>• K201883 HEALIX ADVANCE Self-Punching PEEK & Biocomposite anchors (6.5mm lengths) |
| **Device Classification** | HEALIX ADVANCE KNOTLESS PEEK Anchor and HEALIX ADVANCE SP PEEK Anchor are classified as:<br>Smooth or threaded metallic bone fixation fasteners, classified as Class II, product code MBI, regulated under 21 CFR 888.3040.<br><br>HEALIX ADVANCE KNOTLESS BR Anchor and HEALIX ADVANCE SP BIOCOMPOSITE Anchor are classified as:<br>Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MAI, regulated under 21 CFR 888.3030. |
| **Device Panel** | Orthopedic Devices |
| **Device Description** | The subject devices of this Special 510(k) are the HEALIX ADVANCE Knotless anchors and HEALIX ADVANCE Self-Punching (SP) anchors.<br><br>The HEALIX ADVANCE Knotless Anchor is a one-piece implantable cannulated, threaded anchor designed to secure soft tissue to bone utilizing suture (provided separately). The anchor is preloaded on a disposable inserter shaft with handle, held in place by a #2 ORTHOCORD stay suture comprised of Ultra-High Molecular Weight Polyethylene (UHMWPE) and violet Polydioxanone (PDS). During implantation, the stay suture may be discarded or incorporated into the repair at the surgeon's discretion. The anchor is provided preloaded on a single-use driver. The anchor is offered in three sizes: 4.75mm, 5.5mm and 6.5mm. The |

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| | anchors are available in two materials: Biocryl Rapide® (BR) and Polyetheretherketone (PEEK) materials. The Biocryl Rapide material is a biocomposite material of 70% PLGA copolymer (85% PLLA/15% PGA) and 30% β-TCP. The HEALIX ADVANCE KNOTLESS Anchor is provided sterile and is for single use only.<br><br>The HEALIX ADVANCE SP Anchor is a two-piece "self-punching" design consisting of a cannulated, threaded anchor and dilator designed to secure soft tissue to bone utilizing suture (provided separately). The anchor-dilator are preloaded on a disposable inserter shaft with handle, held in place by a non-absorbable stay suture comprised of Ultra-High Molecular Weight Polyethylene (UHMWPE) and Green poly (ethylene terephthalate) (PET). During implantation, the stay suture may be discarded or incorporated into the repair at the surgeon's discretion. The HEALIX ADVANCE SP Anchor is offered in three sizes: 4.9mm, 5.5mm and 6.5mm. The anchors are available in two materials: Biocomposite (Biocryl) and Polyetheretherketone (PEEK) material. Biocryl is an absorbable biocomposite of Polylactic Acid (PLA) and Tricalcium Phosphate (TCP). The HEALIX ADVANCE SP Anchor is provided sterile and is 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 indications and a modification to the suture compatibility language within the Instructions for Use. |
| **Indications for Use** | HEALIX ADVANCE Knotless anchors (Note: new indications are underlined):<br><br>The DePuy Mitek HEALIX ADVANCE Knotless BR anchors is indicated as follows:<br>• **Shoulder**<br>  ○ Rotator Cuff Repair<br>  ○ Bicep Tenodesis<br>  ○ Deltoid Repair<br>• **<u>Elbow</u>**<br>  ○ <u>Ulnar Collateral Ligament (UCL)</u><br>  ○ <u>Radial Collateral Ligament (RCL)</u><br>• **Knee**<br>  ○ Posterior Oblique<br>  ○ Medial Collateral Ligament (MCL)<br>  ○ Lateral Collateral Ligament (LCL)<br>  ○ Iliotibial (IT) Band Tenodesis<br>  ○ <u>Anterior Cruciate Ligament (ACL) Repair</u><br>  ○ <u>Secondary Fixation in ACL/PCL Reconstruction/Repair</u><br>  ○ <u>Meniscal Root Repair</u><br>• **Foot/Ankle**<br>  ○ Achilles Tendon Repair<br>---------- |

The DePuy Mitek HEALIX ADVANCE KNOTLESS PEEK Anchors is indicated as follows:

- **Shoulder**
  - Rotator Cuff Repair
  - Bicep Tenodesis
  - Deltoid Repair
- **Elbow**
  - Ulnar Collateral Ligament (UCL)
  - Radial Collateral Ligament (RCL)
- **Knee**
  - Posterior Oblique
  - Medial Collateral Ligament (MCL)
  - Lateral Collateral Ligament (LCL)
  - Iliotibial (IT) Band Tenodesis
  - Anterior Cruciate Ligament (ACL) Repair
  - Secondary Fixation in ACL/PCL Reconstruction/Repair
  - Meniscal Root Repair
- **Foot/Ankle**
  - Achilles Tendon Repair
  - Lateral Stabilization
  - Medial Stabilization

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HEALIX ADVANCE Self-Punching anchors (Note: new indications are underlined):

The DePuy Mitek HEALIX ADVANCE SP Biocomposite Anchors is indicated as follows:

- **Shoulder**
  - Rotator Cuff Repair
  - Bicep Tenodesis
  - Deltoid Repair
- **Elbow**
  - Ulnar Collateral Ligament (UCL) reconstruction
  - Radial Collateral Ligament (RCL) reconstruction
- **Knee**
  - Posterior Oblique repair
  - Medial Collateral Ligament (MCL) reconstruction
  - Lateral Collateral Ligament reconstruction
  - Iliotibial (IT) Band Tenodesis
  - Anterior Cruciate Ligament (ACL) Repair
  - Secondary Fixation in ACL/PCL Reconstruction/Repair
  - Meniscal Root Repair

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The DePuy Mitek HEALIX ADVANCE SP PEEK Anchors is indicated as follows:

- **Shoulder**
  - Rotator Cuff Repair

- Bicep Tenodesis
- Deltoid Repair

- **Elbow**
  - Ulnar Collateral Ligament (UCL) reconstruction
  - Radial Collateral Ligament (RCL) reconstruction
- **Knee**
  - Posterior Oblique repair
  - Medial Collateral Ligament (MCL) reconstruction
  - Lateral Collateral Ligament reconstruction
  - Iliotibial (IT) Band Tenodesis
  - Anterior Cruciate Ligament (ACL) Repair
  - Secondary Fixation in ACL/PCL Reconstruction/Repair
  - Meniscal Root Repair
- **Foot/Ankle**
  - Achilles Tendon Repair
  - Lateral Stabilization
  - Medial Stabilization

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| **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 assessment of insertion force. |
| **Safety and Performance** | Results of the analyses demonstrated that the devices continue to meet established design inputs and corresponding criteria, and that there were no new issues of safety or effectiveness related to device performance.<br><br>Based on similarities in the intended use, technological characteristics, and performance in comparison to the predicate devices, the modified HEALIX ADVANCE Knotless anchors and HEALIX ADVANCE Self-Punching anchors have shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act. |