February 5, 2025

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

Re: K243790
Trade/Device Name: GRYPHON™ X Anchor; HEALIX TRANSTEND™ Anchor
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: December 9, 2024
Received: December 10, 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.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
Assistant Director, Biomedical Engineer
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)*

K243790

Device Name

GRYPHON™ X Anchor;
HEALIX TRANSTEND™ Anchor

Indications for Use *(Describe)*

The GRYPHON X Anchor is intended for:

- Shoulder: Biceps Tenodesis;
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Medial Patellofemoral Ligament Reconstruction;
- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

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The HEALIX TRANSTEND Anchor is intended for:

- Shoulder: Rotator Cuff, Partial Thickness Rotator Cuff, Biceps Tenodesis, Acromio-Clavicular Separation, Deltoid Repair;
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Mid-Foot Reconstruction, Hallux Valgus Repair, Metatarsal Ligament/Tendon Repairs;
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis;
- Elbow: Lateral Epicondylitis Repair;
- Wrist: Scapholunate Ligament Reconstruction;
- Hip: Capsular Repair, Acetabular Labral Repair

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.

510(k) Summary

GRYPHON™ X Anchors, HEALIX TRANSTEND™ Anchors

Date Prepared: 02/04/2025

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

Name of Medical Device

Proprietary Name:
A) GRYPHON™ X Anchor
B) HEALIX TRANSTEND™ Anchor

Classification Name:
A) MAI, MBI
B) MBI

Regulation Description:
A) Single/multiple component metallic bone fixation appliances and accessories; Smooth or threaded metallic bone fixation fastener
B) Single/multiple component metallic bone fixation appliances and accessories

Common Name:
A) Suture Anchor
B) Suture Anchor

Substantial Equivalence

The GRYPHON X Anchors are substantially equivalent to the following predicate and reference devices:

Primary Predicate Device:

- K073412 GRYPHON BR Anchors with ORTHOCORD Suture

Additional Predicate Device:

- K090124 GRYPHON BR Anchors with ORTHOCORD Suture

Reference Device(s):

- K103712 GRYPHON PEEK Anchors with ORTHOCORD Suture
- K141259 GRYPHON Anchors with PERMACORD Suture
- K181809 GRYPHON Anchors with DYNACORD Suture

The HEALIX TRANSTEND Anchors are substantially equivalent to the following predicate:

Primary Predicate Device:

- K102298 HEALIX TRANSTEND Anchors

Device Classification

The GRYPHON X Anchors are classified as:

- Smooth or threaded metallic bone fixation fasteners, classified as Class II, product code MBI, regulated under 21 CFR 888.3040; and
- Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MAI, regulated under 21 CFR 888.3030.

The HEALIX TRANSTEND Anchors are classified as:

- Smooth or threaded metallic bone fixation fasteners, classified as Class II, product code MBI, regulated under 21 CFR 888.3040; and

Device Panel

Orthopedic Devices

Device Description

The subject devices of this Traditional 510(k) are the GRYPHON X Anchors and the HEALIX TRANSTEND Anchors.

The proposed GRYPHON X Anchor is suture anchor preloaded on a disposable inserter assembly and is intended for fixation of suture to bone for various orthopedic procedures. The proposed anchor will be available with various suture offerings: ORTHOCORD™ Suture, PERMACORD™ Suture, DYNACORD™ Suture, and PERMATAPE™ 1.3mm Suture, offered in either single strand or double strand configurations with needle attachments. The GRYPHON X Anchors are offered with either a push-in ("P") or threaded ("T") anchor design and are available in absorbable BIOCRYL RAPIDE (BR) (P and T anchors) or non-absorbable PEEK materials (P anchors only). The implant is supplied sterile, ready to use.

	The proposed HEALIX TRANSTEND Anchor is a suture anchor preloaded on a disposable inserter assembly and is intended for fixation of suture bone for various orthopedic procedures. This proposed device will be loaded with either one or two strands of PERMATAPE 1.3mm Suture and will be offered in PEEK material only. The implant is supplied sterile ready to use. The proposed GRYPHON X product portfolio also contains a reusable instrument sterilization tray with lid (sold separately) – it's intended to store and protect the reusable instruments during transport and sterilization
Technological Characteristics	The anchor design, materials, principal of operation, and intended use of the subject devices are identical to that of the predicate devices. The main differences between the proposed devices and predicate devices are the additional suture configurations and additional indications for use (GRYPHON X only).
Indications for Use	The GRYPHON X Anchor is intended for: • **Shoulder:** Biceps Tenodesis; • **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair; • **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Medial Patellofemoral Ligament Reconstruction; • **Elbow**: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction --- The HEALIX TRANSTEND Anchor is intended for: • **Shoulder**: Rotator Cuff, Partial Thickness Rotator Cuff, Biceps Tenodesis, Acromio-Clavicular Separation, Deltoid Repair; • **Foot/Ankle**: Lateral Stabilization, Medial Stabilization, Mid-Foot Reconstruction, Hallux Valgus Repair, Metatarsal Ligament/Tendon Repairs; • **Knee**: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; • **Elbow**: Lateral Epicondylitis Repair; • **Wrist**: Scapholunate Ligament Reconstruction; • **Hip**: Capsular Repair, Acetabular Labral Repair
Non-clinical Testing	Verification activities were assessed for the proposed devices. Verification included an assessment of fixation strength for proposed indications at T=0 and over the healing period (absorbable configuration), insertion force, fatigue strength, as well as an assessment of needle attachment strength for the pre-loaded sutures in scope of the submission.

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. Based on similarities in the intended use, technological characteristics, and performance in comparison to the predicate devices, the proposed GRYPHON X Anchors and HEALIX TRANSTEND Anchors have shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.