July 11, 2022

Medos International SARL
℅ Ashley Aromando (Goncalo)
Regulatory Affairs Project Manager
DePuy Synthes Mitek Sports Medicine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K221364
Trade/Device Name: MITEK TIGHT-N™ Tendon Docking Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 5, 2022
Received: May 12, 2022

Dear Ashley Aromando (Goncalo):

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Laura C. Rose, 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)*
K221364

Device Name
MITEK TIGHT-N™ Tendon Docking Anchor

Indications for Use *(Describe)*
The MITEK TIGHT-N™ Tendon Docking Anchor is indicated for use for reattachment of soft tissue to bone for the following procedures:
• Shoulder: Biceps tenodesis
• Knee: Medial patellofemoral ligament repair/reconstruction (MPFL), posterior oblique ligament repair (POL), medial collateral ligament (MCL) repair, lateral collateral ligament (LCL) repair, anterolateral ligament (ALL) reconstruction, Iliotibial (IT) Band Tenodesis

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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510(K) SUMMARY

MITEK TIGHT-N™ Tendon Docking Anchor

Date Prepared: 07/08/2022

Submitter's Name and Address

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a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

On behalf of:
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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: MITEK TIGHT-N™ Tendon Docking Anchor (also referred to as TIGHT-N™ Anchor)

Classification Name:

Fastener, Fixation, Nondegradable, Soft Tissue

Product Code: MBI
Common Name: Suture Anchor

Substantial Equivalence

The MITEK TIGHT-N™ Tendon Docking Anchor is substantially equivalent to:

- K201749 Arthrex Biocomposite 3.9mm SwiveLock Anchor

Device Classification	The MITEK TIGHT-N™ Tendon Docking Anchor is classified as: Fastener, Fixation, Nondegradable, Soft Tissue, classified as Class II, product code MBI, regulated under 21 CFR 888.3040.
Device Panel	Orthopedic Devices

Device Description	The MITEK TIGHT-N™ Tendon Docking Anchor is designed to reattach soft tissue to bone when used in conjunction with suture (provided separately). The anchor is preloaded on a disposable inserter shaft with handle, held in place by a non-absorbable "stay suture". The proposed anchor will be offered in three sizes: 5.5 mm, 7.0 mm, and 8.5 mm and is molded from PEEK (Polyetheretherketone) material. The proposed anchor is provided sterile via Ethylene Oxide (EO) sterilization and is for single use only.

Technological Characteristics	The anchor design, principal of operation and intended use on MITEK TIGHT-N™ Tendon Docking Anchor are similar when compared to the predicate Arthrex 3.9mm SwiveLock Anchor (K201749). Both devices are implantable anchors used to secure soft tissue to bone. Suture tails of a pre-stitched soft tissue graft (suture provided separately) are threaded through the anchors, thus securing the graft to the anchor. The proposed MITEK TIGHT-N™ Tendon Docking Anchor is designed as a suspensory push-in anchor, while the predicate SwiveLock is designed as an interference thread-in anchor. While there exists differences in the means of insertion style (thread-in vs. push in) and mechanism of tissue retention, the proposed and predicate devices are ultimately securing soft tissue to bone to achieve the device's therapeutic benefit. Both predicate and proposed devices are provided with sutures facilitating placement of the anchor (stay sutures for both the proposed and the predicate device and an additional axillary suture for the proposed MITEK TIGHT-N™ Tendon Docking Anchor). The proposed anchor is constructed from PEEK material, the predicate Arthrex SwiveLock is composed of both PEEK and PLLA/βTCP materials. The PEEK material, of the proposed anchor implant, is identical to the PEEK material of existing Mitek implantable anchors – Versalok Anchors (K100532) Any differences between the proposed device and the predicate are considered non-significant and do not raise different questions of safety or effectiveness, supported by testing.

Indications for Use	The MITEK TIGHT-N™ Tendon Docking Anchor is indicated for use for reattachment of soft tissue to bone for the following procedures: • Shoulder: Biceps tenodesis • Knee: Medial patellofemoral ligament repair/reconstruction (MPFL), posterior oblique ligament repair (POL), medial collateral ligament (MCL) repair, lateral collateral ligament (LCL) repair, anterolateral ligament (ALL) reconstruction, Iliotibial (IT) Band Tenodesis
Non-clinical Testing	Verification activities were performed on the proposed device and / or its predicates. Biocompatibility, shelf-life, pyrogenicity, endotoxin and performance testing conducted on representative products was presented to support determination of equivalence. Performance testing included assessment of fixation strength and fatigue strength. Ethylene Oxide Sterilization was validated according to ANSI/AAMI/ISO 11135: 2014 to a SAL of 1×10^{-6}. EO residuals were tested per AAMI/ANSI/ISO 10993-7:2008 The proposed device has been determined to be non-pyrogenic per the requirements set forth in ANSI/AAMI ST-72:2011, United States Pharmacopeia (USP), and European Pharmacopeia (EP) using the bacterial endotoxin testing (BET) method.
Safety and Performance	Results of performance testing have demonstrated that the proposed devices are suitable for their intended use. Based on similarities in the intended use, technological characteristics, and performance in comparison to the predicate devices, the proposed MITEK TIGHT-N™ Tendon Docking Anchor has shown to be substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.