March 12, 2026

Trax Surgical, Inc.
Shalain Siddiqui
QA/RA Engineer II
75 Mill St.
Stoughton, Massachusetts 02072

Re: K251750
Trade/Device Name: Trax EX Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 10, 2026
Received: February 10, 2026

Dear Shalain Siddiqui:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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, M.S.
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.

510(k) Number*(if known)*

K251750

Device Name

Trax EX Anchor

Indications for Use*(Describe)*

The Trax EX Anchors are intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below:
Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial 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

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

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510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Trax EX Anchor.

Submitted By:	Trax Surgical, Inc. 75 Mill Street Stoughton, MA 02072
Date:	20 November 2025
Contact Person:	Shalain Siddiqui 781.828.4400 ssiddiqui@primomedicalgroup.com
Proprietary Name:	Trax EX Anchor
Common Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name and Reference:	21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener, Class II
Device Product Code, Device Panel:	MBI, Orthopedic
Predicate Device:	Arthrex DX SwiveLock SL with Forked Eyelet (K150648)
Reference Devices:	Arthrex PushLock Anchor (K173240) Arthrex Corkscrew Anchor (K050358) Arthrex Corkscrew Anchor (K003816)

1.0 Device Description

The Trax EX Anchors are intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. The anchors are manufactured from 6AL-4V ELI Titanium. The Trax EX Anchor is a 2-component anchor compromised of the Trax EX Screw-In and the Trax EX Push-In Anchor with diameter sizes ranging from 3.5mm to 5.0mm. The Trax EX Screw-In Anchor is a hollow 6AL-4V ELI titanium anchor that is threaded, preloaded with suture and designed to fixate into bone by way of threaded engagement. The Trax EX Push-In Anchor component is a hollow 6AL-4V ELI titanium anchor that is ribbed, preloaded with suture, and designed to fixate into bone by way of press-fit engagement. Both anchors will be offered in multiple diameters, lengths, and variations in configuration of the distal end of the implant to allow further functional options to the surgeon. The Trax EX Screw-In Anchor is designed to be used alone or in conjunction with the Trax EX Push-In Anchor. The Trax EX Push-In Anchor component is designed to be used only in conjunction with the Trax EX Screw-In Anchor and is not sold separately. The sutures utilized in all implants are high-strength, Ultra High Molecular Weight Polyethylene (UHMWPE). The Trax EX Anchor Delivery

Instruments are intended to prepare the site and fixate the anchors. All kits are intended to be sterilized by ethylene oxide (EO) and provided in a blister tray inside of a Tyvek pouch.

2.0 Indication for Use

The Trax EX Anchors are intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below:

- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
- Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

3.0 Performance Data

Performance of the Trax EX Anchors was evaluated in accordance with ASTM F3690-24 and the FDA guidance *Bone Anchors – Premarket Notification (510(k)) Submissions.* Cyclic pullout testing, static pullout testing, insertion / removal torque testing, and torsional yield strength testing were performed to demonstrate substantial equivalence to the predicate devices. No clinical testing or animal testing was performed.

4.0 Technological Characteristics

The subject Trax EX Anchors have similar technical characteristics as the predicate devices including indications for use, function, and range of sizes.

Trax Surgical has demonstrated that the Trax EX Anchors are safe and effective and perform in a substantially equivalent manner to the predicate devices.

5.0 Conclusion

The subject Trax EX Anchors has been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. Any differences between the subject device and the predicate device are considered minor and do not raise questions concerning safety or effectiveness. The information provided supports equivalence to the predicate device.