



December 04, 2025

Tigon Medical  
Jeremy Clark  
President  
303 Najoles Road  
Suite 104  
Millersville, Maryland 21108

Re: K252596

Trade/Device Name: Tigon Medical Knotless and Dual Javelin All-Suture Anchors  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener  
Regulatory Class: Class II  
Product Code: MBI  
Dated: October 30, 2025  
Received: October 30, 2025

Dear Jeremy Clark:

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](mailto: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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252596

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Please provide the device trade name(s).

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Tigon Medical Knotless and Dual Javelin All-Suture Anchors

Please provide your Indications for Use below.

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The Tigon Medical Knotless and Dual Javelin All-Suture Anchors are an extension to the Tigon Medical All-Suture Anchor line cleared in K242529 (December 20, 2024). The Tigon Medical Javelin All-Suture Anchors are intended for the reattachment of soft tissue to bone for the following indications:

- 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 Repair
- Hand/Wrist: Scaphulolunate Ligament Reconstruction, Carpal 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 Repair
- 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
- Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair

Please select the types of uses (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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## Submitter Information

**Applicant:** Tigon Medical

**Contact Person:** Jeremy Clark  
Management Representative  
Tigon Medical  
303 Najoles Rd.  
Millersville, MD 21108  
(410) 544-2833

**Date Prepared:** 02DEC2025

**Name of Device:** Tigon Medical Knotless and Dual Javelin All-Suture Anchors

**Common Name:** Fastener, Fixation, Nondegradable, Soft Tissue

**Classification Name:** 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener

**Regulatory Class:** II

**Product Code/Panel:** MBI

**Predicate Devices:** Tigon Medical All-Suture Anchors (K242529) [Primary Predicate]  
Arthrex Knotless FiberTak Suture Anchor (K130458)  
Reference: Threadstone HyperSuture (K230311)  
Reference: Tigon Medical Tomahawk Anchors, Dual Anchors, Eye-Deal Anchors, Tenodesis Anchors (K220464)  
Reference: Tigon Medical Tissue Anchors (K182507)

# K252596 510(k) Summary



## Indications for Use:

The Tigon Medical Knotless and Dual Javelin All-Suture Anchors are an extension to the Tigon Medical All-Suture Anchor line cleared in K242529 (December 20, 2024). The Tigon Medical Javelin All-Suture Anchors are intended for the reattachment of soft tissue to bone for the following indications:

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- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
- Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair

## Device Description Summary:

The Tigon Medical Knotless and Dual Javelin All-Suture Anchors are an extension to the Tigon Medical All-Suture Anchor line cleared in K242529 (December 20, 2024). The Knotless Javelin All-Suture Anchor serves as a soft tissue fixation device that enhances surgical efficiency by eliminating the need for knot tying. The Dual Javelin All-Suture Anchor enhances the line by creating a double sock, knotless construct, eliminating the steps of tying a knot and passing suture through tissue. The devices are UHMWPE per ASTM F2848, permanent, soft-tissue fixation devices provided EtO sterilized and

preloaded on an inserter. The anchors, available in 1.6 mm, 2.3 mm, and 2.6 mm sizes, come in various load configurations consisting of one or more working sutures, USP 2 suture cable, 1.5 mm suture tape, USP 5 suture cable, and/or 2 mm suture tape. The anchors can be implanted via self-punching or drilling and are intended to deploy under the cortical layer of the bone. The inserters can be reprocessed after use and are made from stainless steel. The device is intended for single-use in a surgical setting.

### **Substantial Equivalence Summary:**

The Tigon Medical Knotless and Dual Javelin All-Suture Anchors are substantially equivalent to the predicate devices as the technological characteristics, features, and intended uses are the same. Mechanical testing was performed to verify the fixation strength of the candidate devices as compared to the predicate.

Substantial equivalence between the Tigon Medical Knotless and Dual Javelin All-Suture Anchors and the predicates can be demonstrated according to the FDA's Guidelines for Substantial Equivalence Decision Making Process, for at least the following reasons:

- The candidate devices have equivalent intended use and indications as the predicate devices.
- Major technological characteristics are substantially equivalent between the candidate devices and the predicate devices including, but not limited to:
  - Substantially equivalent materials
  - Substantially equivalent size range
  - Substantially equivalent method of fixation
  - Substantially equivalent mechanical strength

### **Non-Clinical Testing Summary:**

Tigon Medical substantiates that the product is as safe, as effective, and performs as well as or better than the legally marketed predicate.

## K252596 510(k) Summary



Comparative mechanical testing, including fatigue testing, displacement after fatigue testing, and axial pull out testing, was performed according to ASTM F3690-24 and ASTM F543. The mechanical test data demonstrates that the Tigon Medical Knotless and Dual Javelin All-Suture Anchors are substantially equivalent to the predicate device identified.