April 21, 2026

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

Re: K260921
Trade/Device Name: Tigon Medical Static Javelin All-Suture Anchors & Javelin All-Suture Anchor Line
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 19, 2026
Received: March 19, 2026

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 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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K260921

Device Name
Tigon Medical Static Javelin All-Suture Anchors & Javelin All-Suture Anchor Line

Indications for Use *(Describe)*
The Tigon Medical 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

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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TIGON MEDICAL

Submitter Information

Applicant:	Tigon Medical
Contact Person:	Jeremy Clark Management Representative Tigon Medical 303 Najoles Rd. Millersville, MD 21108 (410) 544-2833
Date Prepared:	19MAR2026
Name of Device:	Tigon Medical Static Javelin All-Suture Anchors & Javelin All-Suture Anchor Line
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 Knotless and Dual Javelin All-Suture Anchors (K252596) Additional: Tigon Medical All-Suture Anchors (K242529) Additional: Tigon Medical Tomahawk Anchors, Dual Anchors, Eye-Deal Anchors, Tenodesis Anchors (K220464) Additional: Tigon Medical Tissue Anchors (K182507) Reference: Threadstone HyperSuture (K230311)

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Intended Use:

The Tigon Medical 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

Device Description Summary:

The Tigon Medical Static Javelin All-Suture Anchors are an extension of the Tigon Medical All-Suture Anchor line cleared in K242529 (December 20, 2024) and the Tigon Medical Knotless and Dual All-Suture Anchors cleared in K252596 (December 4, 2026). The Static Javelin All-Suture Anchors are a combination of the suture used in a Dual All-Suture Anchor as well as components of the sliding Javelin All-Suture Anchor and the Knotless Javelin All-Suture Anchor. The extension to the original line is a 2.3 mm x 16.5 mm double loaded all-suture anchor. The devices are soft-tissue fixation devices provided EtO sterilized, preloaded on an inserter. The anchor consists of different load configurations consisting of one or more working sutures, USP 2 suture cable and/or 1.5 mm suture tape, with either a single sliding suture, knotless anchor, or standalone. The anchors can be implanted via self-punching, pre-awling, or drilling. The inserters can be

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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 Javelin All-Suture Anchors & Extension to Javelin All-Suture Anchor Line are substantially equivalent to the predicate devices as the 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 candidate devices and the predicate devices can be demonstrated according to the FDA's Guidelines for Substantial Equivalence Decision Making Process, for at least the following reasons:

- The candidate device has equivalent intended use and indications as the predicate device.
- 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.

Comparative mechanical testing, including fatigue testing, displacement after fatigue testing, and axial pull out testing, was performed according to ASTM F3690-24. The mechanical test data demonstrates that the candidate devices are substantially equivalent to the predicate devices identified.