March 22, 2023

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

Re: K220464
Trade/Device Name: Tomahawk Anchors, Dual Anchors, Eye-Deal Anchors, Tenodesis Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 24, 2023
Received: February 28, 2023

Dear Mr. 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 (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,

Sara S. Thompson -S

For

Laurence D. Coyne, Ph.D.
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)*
K220464

Device Name
Tigon Medical Gryphon Anchor Line

Indications for Use *(Describe)*
The Tigon Medical Gryphon Anchor Line is made up of four families of soft tissue fixation devices: Tomahawk Anchor, Dual Anchor, Eye-Deal Anchor, and Tenodesis Anchors. The entirety of the gryphon anchor line is intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Capsular stabilization (Bankart repair, Anterior shoulder instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstructions), Acromioclavicular separation repairs, Deltoid repairs, Rotator cuff repairs, Bicep tenodesis.

Elbow, Wrist, and Hand: Biceps tendon reattachment, Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair;

Knee: Extra-capsular repairs (Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament), Patellar realignment and tendon repairs (Vastus medialis obliquus advancement), Iliotibial band tenodesis;

Foot and Ankle: Hallux valgus repairs, Medial or Lateral instability repairs/reconstructions, Achilles tendon repairs/ reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repairs/reconstructions, Bunionectomy

In addition to these indications, the Tenodesis Anchors, a sub family of the gryphon anchor line will also be indicated for:

Foot and Ankle: Flexor hallucis longus for Achilles tendon reconstructions, tendon transfers in the foot and Ankle

Knee: ACL Repair

Hand/Wrist: Carpometacarpal joint arthroplasty, carpal ligament reconstructions and repairs, tendon transfer in hand/wrist

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

TIGON MEDICAL

Submitter Information

Applicant:	Tigon Medical
Submission Number:	K220464
Contact Person:	Jeremy Clark Management Representative Tigon Medical 303 Najoles Rd. Millersville, MD 21108 (410) 544-2833
Date Prepared:	03/22/2023
Name of Device:	Tigon Medical Gryphon Anchor Line
Common Name:	Fastener, Fixation, Nondegradable, soft tissue
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
Product Code/Panel:	MBI
Predicate Devices:	Tigon Medical Tissue Anchors (K182507) Reference: Tigon Medical Button System (K211049) Reference: Arthrex Tenodesis Family (K051726) Reference: Smith and Nephew Bioraptor (K151105)

510(k) Summary

Intended Use:
The Tigon Medical Gryphon Anchor Line is made up of four families of soft tissue fixation devices: Tomahawk Anchor, Dual Anchor, Eye-Deal Anchor, and Tenodesis Anchors. The entirety of the gryphon anchor line is intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Capsular stabilization (Bankart repair, Anterior shoulder instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstructions), Acromioclavicular separation repairs, Deltoid repairs, Rotator cuff repairs, Bicep tenodesis.

Elbow, Wrist, and Hand: Biceps tendon reattachment, Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair;

Knee: Extra-capsular repairs (Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament), Patellar realignment and tendon repairs (Vastus medialis obliquus advancement), Iliotibial band tenodesis;

Foot and Ankle: Hallux valgus repairs, Medial or Lateral instability repairs/reconstructions, Achilles tendon repairs/ reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repairs/reconstructions, Bunionectomy

In addition to these indications, the Tenodesis Anchors, a sub family of the gryphon anchor line will also be indicated for:

Foot and Ankle: Flexor hallucis longus for Achilles tendon reconstructions, tendon transfers in the foot and Ankle

Knee: ACL Repair

Hand/Wrist: Carpometacarpal joint arthroplasty, carpal ligament reconstructions and repairs, tendon transfer in hand/wrist

510(k) Summary

Device Description Summary:
The Tigon Medical Gryphon Anchor Line consists of four sub-families of suture anchors: Tomahawk anchors, Dual anchors, Tenodesis anchors, and Eye-Deal anchors. It consists of a range of anchors sizes between 3.75 mm diameter and 6 mm length to 10.5 mm diameter and 23 mm length. The Tomahawk Anchors, Dual Anchors, and Tenodesis anchors are made from VESTAKEEP® i4R PEEK per ASTM F2026 while the Eye-Deal Anchors are made from Ti6Al4V ELI per ASTM F136.

The anchors are available with many configurations of sutures and suture tapes or without suture. All the anchors in this system may be loaded with a combination of USP #2 suture cables and/or tape equivalent while the Dual Anchors and Tenodesis anchors may be loaded with a combination of USP 2 *and* USP 5 suture cables and/or tape equivalent.

All anchors are inserted with stainless steel inserters per ASTM F899. The shafts that are used with the Tomahawk anchors may be reprocessed and will be available sterile packed and attached to the anchor and suture.

Substantial Equivalence Summary:

The Tigon Medical Gryphon anchor line is made of four sub-families: Tomahawk Anchors, Dual Anchors, Eye-Deal Anchors, and Tenodesis Anchors. All four sub-families are substantially equivalent to the predicate devices as the features and intended use are the same. The indications for use differ between the Tenodesis anchors and the rest of the product family made up by the other Gryphon anchor sub-families. Those additional indications for use are found in the reference device: K051726 (Arthrex Tenodesis Family). Anchor fixation has been shown to be a biomechanically sound method of soft tissue to bone fixation. Mechanical testing has been done, including cyclical loading and tensile strength which demonstrated the proposed products met the acceptance criteria for the proposed indications.

510(k) Summary

Characteristics	Tigon Medical Gryphon Anchor Line	Tigon Medical Tissue Anchors	Substantial Equivalence
Product Codes	MBI	MBI	Yes
510(k) Number	K220464	K121018	
Indications	The Tigon Medical Gryphon Anchor Line is made up of four families of soft tissue fixation devices: Tomahawk Anchor, Dual Anchor, Eye-Deal Anchor, and Tenodesis Anchors. The entirety of the gryphon anchor line is intended for use for the reattachment of soft tissue to bone for the following indications: Shoulder: Capsular stabilization (Bankart repair, Anterior shoulder instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstructions), Acromioclavicular separation repairs, Deltoid repairs, Rotator cuff repairs, Bicep tenodesis.	The Tigon Medical Tissue Anchor System is intended for use for the reattachment of soft tissue to bone for the following indications: Shoulder: Capsular stabilization (Bankart repair, Anterior shoulder instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstructions), Acromnioclavicular separation repairs, Deltoid repairs, Rotator cuff repairs, Bicep tenodesis; Elbow, Wrist, and Hand: Biceps tendon reattachmnent, Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair; Knee: Extra-capsular repairs (Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament),	Yes, when also considering the referenced devices. The Arthrex tenodesis family (K051726) have the same added indications as the tenodesis anchors, a sub family in the Tigon Medical Gryphon Anchor line. (In addition to these indications, the Tenodesis Anchors, a sub family of the gryphon anchor line will also be indicated for: Foot and Ankle: Flexor hallucis longus for Achilles tendon reconstructions, tendon transfers in the foot and Ankle Knee: ACL Repair Hand/Wrist: Carpometacarpal joint arthroplasty, carpal

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Characteristics	Tigon Medical Gryphon Anchor Line	Tigon Medical Tissue Anchors	Substantial Equivalence
	Elbow, Wrist, and Hand: Biceps tendon reattachment, Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair; Knee: Extra-capsular repairs (Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament), Patellar realignment and tendon repairs (Vastus medialis obliquus advancement), Iliotibial band tenodesis; Foot and Ankle: Hallux valgus repairs, Medial or Lateral instability repairs/reconstructions, Achilles tendon repairs/ reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon	Patellar realignment and tendon repairs (Vastus medials obliquous advancement), Illiotibial band tenodesis; Foot and Ankle: Hallux valgus repairs, Medial or Lateral instability repairs/reconstructions, Achilles tendon repairs/ reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repairs/reconstructions, Bunionectomy	ligament reconstructions and repairs, tendon transfer in hand/wrist)

Characteristics	Tigon Medical Gryphon Anchor Line	Tigon Medical Tissue Anchors	Substantial Equivalence
	repairs/reconstructions, Bunionectomy In addition to these indications, the Tenodesis Anchors, a sub family of the gryphon anchor line will also be indicated for: Foot and Ankle: Flexor hallucis longus for Achilles tendon reconstructions, tendon transfers in the foot and Ankle Knee: ACL Repair Hand/Wrist: Carpometacarpal joint arthroplasty, carpal ligament reconstructions and repairs, tendon transfer in hand/wrist		
Sizes	The Tigon Medical Gryphon Anchor Line is made up of a range of sizes.	The Tigon Medical Tissue anchors is made up of a range of sizes.	Yes, when also considering the referenced devices. The tenodesis anchors have a larger size range

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Characteristics	Tigon Medical Gryphon Anchor Line	Tigon Medical Tissue Anchors	Substantial Equivalence
			than the Tigon Medical Tissue Anchors, but this range is identical to the range of the referenced Arthrex Tenodesis Family anchors (K051726)
Mechanical Strength	The worst case implant in the Tigon Medical Gryphon Anchor Line has a mechanical strength of 262.3 N	The worst-case implant in the Tigon Medical Tissue Anchor line has a mechanical strength of 143.6 N	Yes
Fatigue Testing	Up to 500 cycles were done from unloaded (5N) to loaded(60N) condition until failure.	Up to 500 cycles were done from unloaded (5N) to loaded(60N) condition until failure.	Yes
Material	PEEK per ASTM F2026 or Ti-6AL-4V ELI Titanium per ASTM F-136	PEEK Per ASTM F2026	Yes For Titanium see reference device Tigon Medical Button System made from TI6AI4V ELI Per ASTM F136. (K211049)
Method of fixation	Interference or screw in	Push in, or screw in	Yes, when also considering the referenced devices. The tenodesis anchors have an identical method of fixation (interference) as the referenced Arthrex

510(k) Summary

Characteristics	Tigon Medical Gryphon Anchor Line	Tigon Medical Tissue Anchors	Substantial Equivalence
			Tenodesis Family anchors (K051726)
Inserter	Multi-piece (2 or 3) reusable inserter. Anchors may come preloaded with suture on an inserter shaft or be loaded on an inserter at time of surgery.	Multi-piece (2) reusable inserter. Anchors may come preload with suture and will be loaded on the inserter at the time of surgery	Yes
Drills/Awls	Anchors will be inserted into pilot holes appropriate for their size	Anchors are inserted into pilot holes appropriate to their size.	Yes
Cannulas	Drill Guide	Drill Guide	Yes
Supplied	All Implants: Sterile to assure an SAL of 10^{-6} One inserter type: Sterile to assure an Sterile to assure an SAL of 10^{-6} All other inserters: Non Sterile, to be sterilized on site in tray	All Implants: Sterile to assure an SAL of 10^{-6} All other inserters: Non Sterile, to be sterilized on site in tray	Yes

510(k) Summary

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.

Tests performed:

Axial Pullout Strength: The device was found to be substantially equivalent to the predicate for maximum pullout strength per ASTM F543.

Fatigue Testing: The device was found to be substantially equivalent to the predicate for cyclic loading fatigue testing.

Insertion Performance Testing: The device was found to be substantially equivalent to the predicate product.

Sterilization Validation activities including EO Residual Testing, Sterility Testing, and Bioburden Testing.

Endotoxin testing has been conducted and will be continuously monitored on a lot-by-lot basis.

Accelerated Shelf-Life Testing and Packaging Performance/integrity testing has been conducted and real-time shelf-life testing is on-going.

Biocompatibility Summary:

The device in its final finished form has been evaluated for biocompatibility according to ISO10993-1.

510(k) Summary

Device Comparison Discussion:
Substantial equivalence between the Tigon Medical Gryphon Anchor Line and the Tigon Medical Tissue Anchors can be demonstrated according to the FDA's Guidelines for Substantial Equivalence Decision Making Process, for at least the following reasons:

- The Tigon Medical Gryphon Anchor Line is compared to the Tigon Medical Tissue Anchors
- The Tigon Medical Gryphon Anchor Line has equivalent intended use and indications as the Tigon Medical Tissue Anchor
- Major technological characteristics are substantially equivalent between the Tigon Medical Gryphon Anchor Line and the Tigon Medical Tissue Anchor
- including, but not limited to:
    - Substantially equivalent materials*
    - Substantially equivalent size range**
    - Substantially equivalent method of fixation
    - Substantially equivalent mechanical strength

*The Eye-Deal anchor is titanium which is identical to that of the reference device: Tigon Medical Button System (K211049)

**The Tenodesis Anchors exceed the size range of the Tigon Medical Tissue Anchor, but is substantially equivalent to that of the Arthrex Tenodesis Family anchors (K051726). The indications for use of the Tenodesis anchors match that of the Arthrex Tenodesis Family anchors (K051726)