August 4, 2021

Tigon Medical
Jeremy Clark
Management Representative
838 Ritchie Hwy, Suite 5
Severna Park, Maryland 21146

Re: K211049
Trade/Device Name: Tigon Medical Button System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 25, 2021
Received: July 2, 2021

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,

for

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)*
K211049

Device Name
Tigon Medical Button System

Indications for Use *(Describe)*
Indications for Use:
The Tigon Medical Button System implants are intended to facilitate fixation of bone to bone or soft tissue to bone.
Shoulder:
Proximal Biceps Tendon Repair
Minor Pectoralis Repair
Major Pectoralis Repair
Elbow:
Distal Biceps Tendon Repair
Ulnar Collateral Ligament Reconstruction
Knee:
Anterior Cruciate Ligament Repair
Posterior Cruciate Ligament 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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5. 510(k) Summary

K211049

Submitter Information

Applicant:	Tigon Medical
Contact Person:	Jeremy Clark Management Representative Tigon Medical 838 Ritchie Hwy, Suite 5 Severna Park, MD 21146 (410) 544-2833
Date Prepared:	4/7/2021
Name of Device:	Tigon Medical Button System
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:	Arthrex Biceps Button (K123341)
Intended Use:	The Tigon Medical Button System implants are intended to facilitate fixation of bone to bone or soft tissue to bone. Shoulder: Proximal Biceps Tendon Repair Minor Pectoralis Repair Major Pectoralis Repair

5. 510(k) Summary

Elbow:

Distal Biceps Tendon Repair
Ulnar Collateral Ligament Reconstruction

Knee:

Anterior Cruciate Ligament Repair
Posterior Cruciate Ligament Repair

Device Description:

The Tigon Medical Button System is comprised of reusable instrumentation and button implants designed to interface together in order to secure soft tissue to bone and fixate bone to bone. The reusable instrumentation is designed to operate with any grouping of available buttons within the system. Each button is made of titanium and designed to be used with #2 suture cable or 1.4 mm to 2 mm suture tapes. Each button is made up of very similar eyelet geometry and a thickness of 2 mm. The button widths vary from 2.25 mm to 2.7 mm. The lengths of the buttons vary from 6.65 mm to 8 mm. The buttons are designed to function against a single cortex by resting in the intramedullary cavity or against the cortex on the opposite side of the fixation site.

Substantial Equivalence Summary:

The Tigon Medical Button System is substantially equivalent to the predicate devices as the features and intended uses are the same. Button fixation has been shown to be a biomechanically sound method of soft tissue and bone to bone fixation. Mechanical testing has been done, including cyclical loading and tensile strength which demonstrated the proposed product met the acceptance criteria for the proposed indications.

5. 510(k) Summary

Characteristics	Tigon Medical Button System	Arthrex Biceps Button	Substantial Equivalence (Yes or No)
Product Codes	MBI	MBI	Yes
510(k) Number	K211049	K123341	
Indications	Indications for Use: The Tigon Medical Button System implants are intended to facilitate fixation of bone to bone or soft tissue to bone. **Shoulder:** Proximal Biceps Tendon Repair Minor Pectoralis Repair Major Pectoralis Repair **Elbow:** Distal Biceps Tendon Repair	The Suture Button and RetroButton are used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. The BicepsButton, Pec Button and Tenodesis Button are used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the shoulder and elbow	Yes

5. 510(k) Summary

Characteristics	Tigon Medical Button System	Arthrex Biceps Button	Substantial Equivalence (Yes or No)
	Ulnar Collateral Ligament Reconstruction **Knee:** Anterior Cruciate Ligament Repair Posterior Cruciate Ligament Repair	Shoulder: Pectoralis Repair (Minor/Major) Biceps Tendon Repair (Distal/Proximal) Ulnar Collateral Ligament Reconstruction Knee: ACL Repair	
Button - Sizes	The Tigon Medical Button System is made up of a range of button sizes.	The Arthex Biceps Button is made up of a variety of different button combinations and sizes.	Yes
Button - Mechanical Strength	The Tigon Medical Button System has an average mechanical pull out strength of 289.55N	The Arthrex Bicep Button has an average mechanical pull out strength of 283.15N	Yes

5. 510(k) Summary

Characteristics	Tigon Medical Button System	Arthrex Biceps Button	Substantial Equivalence (Yes or No)
Fatigue Testing	Up to 4000 cycles were done from unloaded (5N) to loaded (225N) condition until failure. Average failure occurred at 909 cycles.	Up to 4000 cycles were done from unloaded (5N)to loaded (225N) condition until failure. Average failure occurred at 855 cycles.	Yes
Button - Material	Ti-6Al-4V ELI Titanium per ASTM F-136	Ti-6Al-4V ELI Titanium per ASTM F-136	Yes
Button – Method of fixation	Unicortical and bicortical	Unicortical and bicortical	Yes
Inserter	Multi-piece (3) reusable inserter. Button loaded onto inserter during surgery	Multi-piece (2) disposable inserter. Button loaded onto inserter in packaging prior to surgery	Yes
Drills	(2.6mm – 3.2 mm) Drill bits for biceps. Drill appropriate sized holes to ensure proper button insertion.	3.2 mm drill (Biceps Button), 4 mm drill pin (Retro Button)	Yes
Cannulas	Drill Guide	Drill Guide	Yes

5. 510(k) Summary

Characteristics	Tigon Medical Button System	Arthrex Biceps Button	Substantial Equivalence (Yes or No)
Supplied	Buttons and instruments shipped sterile and non-sterile.	Buttons and instruments shipped sterile.	Yes, Buttons shipped non-sterile to be steam sterilized such as the referenced AOS Small Fragment Plating System consisting of Titanium screws (K152732)

Non-Clinical Testing Summary:

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

Tray Sterilization Validation: The Tigon Medical Button system was found to be sterile in the Tigon Medical Shoulder Set.

Device Comparison Discussion:

5. 510(k) Summary

Substantial equivalence between the Tigon Medical Button System can be demonstrated according to the FDA's Guidelines for Substantial Equivalence Decision Making Process, for at least the following reasons:

- The Tigon Medical Button System is compared to the Arthrex Biceps Button
- The Tigon Medical Button System has equivalent intended use and indications as the Arthrex Biceps Button
- Major technological characteristics are substantially equivalent between the Tigon Medical Button System and the Arthrex Biceps Button
- including, but not limited to:
    - Substantially equivalent materials
    - Substantially equivalent size range
    - Substantially equivalent method of fixation
    - Substantially equivalent mechanical strength