January 21, 2019

Tigon Medical
% Lee Strnad
President
Intrepid Orthopedics, LLC
3953 Humphrey Road
Richfield, Ohio 44286

Re: K182507
Trade/Device Name: Tigon Medical Tissue Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 21, 2018
Received: November 23, 2018

Dear Mr. Strnad:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182507

Device Name
Tigon Medical Tissue Anchors

Indications for Use *(Describe)*
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), 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

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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05. 510(k) Summary

Submitter Information

Applicant: Tigon Medical

Contact Person: Lee A. Strnad
Management Representative
Intrepid Orthopedics
3953 Humphrey Rd
Richfield, OH 44286
(440) 465-4321

Date Prepared: 8/7/18

Name of Device: Tigon Medical Tissue Anchor

Common Name: Tissue/Suture Anchor

Classification Name Smooth or threaded metallic bone fixation fastener (per 21 CFR 888.3040)

Product Code/Panel: MBI

Predicate Devices: Smith and Nephew BIORAPTOR Knotless Suture Anchors (K121018)

Cayenne Medical Quattro Link Knotless Anchor (K122314)

Intended Use:

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

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- Lateral epicondylitis repair
- Knee
  - Extra-capsular repairs
    - Medial collateral ligament
    - Lateral collateral ligament
    - Posterior oblique ligament
  - 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

Device Description

The Tigon Medical Tissue Anchor System consists of multiple-sized medial, lateral tissue anchors, and a single sized labral anchor. The medial anchors are threaded and are offered in 5.5 and 6.5 mm outer diameter sizes. The lateral anchors are conically barbed and are offered in 4.8 and 6 mm outer diameter sizes. The lateral anchors also offer unique angled locking slits to eliminate the need for knotting to secure the suture. The labral anchors are also barbed, and are offered in a 2.9 mm outer diameter, and are available with grooves, and two groove-less, knotless varieties (with and without locking slit). Tigon Tissue Anchors can be used with Tigon 2mm CuffTape and Tigon #2CuffCable (sold separately). Each tissue anchor will have a similar inserter.

Technological Characteristics

The Tigon Medical Tissue Anchors have the same intended use as the predicate devices. The Tigon Medical Tissue Anchors have similar indications for use as the predicate devices. The Tigon Medical Tissue Anchors are manufactured from the same material as the predicate devices. Tigon Medical Tissue Anchor implants are manufactured from PEEK per ASTM F-2026 or equivalent. The range of sizes of the Tigon Medical Tissue Anchors are similar to the predicate devices.

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Non-Clinical Performance Data Summary

1. ASTM F-543 Testing
2. Limulus Amebocyte Lysate (LAL) Testing
3. Material-Mediated Pyrogen (MMP) Testing
4. Pre-validated Medical Packaging: Sealing and five year real time aging of QSEAL® pouch packaging systems per ASTM F1886/F1886M, ASTM F88/F88M, ASTM F1929, and ISO 11137-1.
5. Instrument Cleaning validation as outlined by AAMI TIR12-2010
6. Pre-vac steam sterilization validation per ANSI/AAMI ST79:2017
7. Pre-vac drying time validation per ANSI/AAMI ST79:2017

Clinical Performance Data Summary

No clinical testing was required.

Non-Clinical and Clinical Performance Data Conclusions

The Tigon Medical Tissue Anchors implants are manufactured from well-known biocompatible material PEEK (ASTM F2026). The Tigon Medical Tissue Anchors material, PEEK, of the final device is identical to the predicate device in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents). No Biocompatibility testing was necessary.

Endotoxin, Pyrogenicity, Sterility, Shelf life, Packaging, and Mechanical testing has been completed. The test results concluded that the Tigon Medical PEEK Anchors Package System passed all pre-determined acceptance criteria and is substantially equivalent to current predicate systems.

Based on testing results and the comparisons provided, the Tigon Medical Tissue Anchors are considered substantially equivalent to the Knotless Suture Anchors (K121018) and the Cayenne Medical Quattro Link Knotless Anchor (K122314) in material, construction, and performance characteristics.