October 29, 2024

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

Re: K240175
Trade/Device Name: Tigon Medical Fractures, Instability, and Reconstruction (FIRE)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HRS
Dated: October 3, 2024
Received: October 4, 2024

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240175

Device Name

Tigon Medical Fractures, Instability, and Reconstruction (FIRE)

Indications for Use *(Describe)*

The Tigon Medical FIRE System is intended to provide the orthopedic surgeon with a means of bone-to-bone fixation and to assist in the management of reconstructive surgeries.
- Bone Loss Deficiencies/Deformities
  - Latarjet
  - Free bone block
- Internal bone fixation for bone fractures, fusions, non-unions, and osteotomies in the foot, ankle, hand, and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K240175 510(k) Summary

TIGON MEDICAL

Submitter Information

Applicant:	Tigon Medical
Contact Person:	Jeremy Clark Management Representative Tigon Medical 303 Najoles Rd. Millersville, MD 21108 (410) 544-2833
510(k) Number:	K240175
Date Prepared:	03OCT2024
Name of Device:	Tigon Medical Fractures, Instability, and Reconstruction (FIRE) System
Common Name:	Screw, Fixation, Bone
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
Product Code/Panel:	HWC, HRS
Predicate Devices:	Latarjet Cortical Screw Set (K083096) Arthrex Low Profile Plate and Screw System (K052614)

Intended Use:

The Tigon Medical FIRE System is intended to provide the orthopedic surgeon with a means of bone-to-bone fixation and to assist in the management of reconstructive surgeries.

- Bone Loss Deficiencies/Deformities
  - Latarjet
  - Free bone block
- Internal bone fixation for bone fractures, fusions, non-unions, and osteotomies in the foot, ankle, hand, and wrist.

Device Description Summary:
The Tigon Medical Fractures, Instability, and Reconstruction (FIRE) System includes reconstruction devices that are designed to provide a means of bone-to-bone fixation and to assist in the management of reconstructive surgeries. The system includes instruments that allow for the placement of the reconstruction device and screws. The reconstruction devices and screws are available in various sizes.

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.

Mechanical testing was performed according to ASTM F543 and ASTM F382. The FDA guidance documents, Orthopedic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway and Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway, were utilized to prove substantial equivalence. The mechanical test data demonstrates that the torsional strength, torque, and pullout strength have met the acceptance criteria for the proposed indications.

Substantial Equivalence Summary:
The Tigon Medical Fractures, Instability, and Reconstruction (FIRE) System is substantially equivalent to the predicate devices as the features and intended uses are the same. Any variations between the candidate devices and the predicate devices are considered minor and do not raise any issues concerning safety or effectiveness. The mechanical test data demonstrates that the torsional strength, torque, and pullout strength have met the acceptance criteria for the proposed indications.