December 21, 2022

TriMed, Inc.
% David Anderson
Principal Consultant
Tech2Med, LLC
6450 Old Darby TRL NE
Ada, Michigan 49301

Re: K222637
Trade/Device Name: TriMed Wrist Fixation System 3
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, NDL, NDG
Dated: November 22, 2022
Received: November 22, 2022

Dear David Anderson:

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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)*

K222637

Device Name
TriMed Wrist Fixation System 3

Indications for Use *(Describe)*

TriMed Volar Plates and Radial Peg Plates
The following fracture configurations may be applicable for treatment using the TriMed Volar Plates and Radial Peg Plates:
1. Fractures, non-unions or osteotomies of the distal radius.

TriMed Ulnar Peg Plates
Fractures, non-unions and osteotomies of the distal end of the ulna.

TriMed Pin Plates
The following fracture configurations may be applicable for treatment using the TriMed Pin Plates:
1. Fractures of the radial column of the wrist.
2. Fractures of the dorsal ulnar cortex of the distal radius.

TriMed Wire Forms and Hook Plates
Fragments of the distal radius large enough to allow intraosseous support from the device with an adjacent stable cortex of cortical bone.

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

Submitted By:	TriMed, Inc. 27533 Avenue Hopkins Santa Clarita, CA 91355 United States of America
Contact Person:	David Anderson Principle Regulatory Consultant Office – (574) 377-0111 Fax – (661) 254-8485
Date:	December 21, 2021
Proprietary Name:	TriMed Wrist Fixation System 3
Common Name(s):	Plate, Fixation, Bone Screw, Fixation, Bone Pin, Fixation, smooth Washer, Bolt, Nut, Non-Spinal Metallic
Classification Name:	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories (Primary). 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class:	II
Product Codes:	HRS, HWC, NDL, NDG
Predicate Device:	Primary Predicate K040112 – TriMed Bearing Plate / TriMed Volar Bearing Plate, TriMed, Inc. (USA) Additional Predicate Devices K951302 – Small Fragment Plates and Screws, MEDPAC. (USA) K951303 – Small Fragment Clamp and Buttress, MEDPAC, (USA) K010545 – Tension Band Wires, TriMed, (USA)

Device Description

TriMed Volar Plates consist of anatomically shaped plates used for fractures, non-unions or osteotomies of the distal radius. TriMed Bearing plates utilize distal bearings to allow peg angulation up to 30 degrees. Fixed Angle Volar Plates have pre-defined peg-hole trajectories. TriMed Fixed Angle and Bearing Plates are compatible with 2.4mm locking pegs and 2.4mm non-locking cortical bone screws distally and 3.2mm screws proximally.

TriMed Wrist Hook Plates are anatomically shaped plates used for fragments of the distal radius large enough to allow intraosseous support from the device with an adjacent stable cortex of cortical bone. TriMed Wrist Hook Plates are compatible with 2.4mm screws and locking pegs.

TriMed Radial Peg Plates are anatomically shaped for the radial column used for fractures, non-unions or osteotomies of the distal radius. TriMed Radial Peg Plates are compatible with 2.4mm screws and locking pegs.

TriMed Ulnar Peg Plates are semi-tubular straight plates used for fractures, non-unions and osteotomies of the distal end of the ulna. TriMed Ulnar Peg Plates are compatible with 2.4mm screws and locking pegs.

TriMed Pin Plates are anatomically shaped plates used for the treatment of fractures of the radial column of the wrist and fractures of the dorsal ulnar cortex of the distal radius. TriMed Pin Plates are compatible with 1.1mm k-wires and 2.4mm screws.

TriMed Buttress Pins are wire forms that are contoured to be used for fragments of the distal radius large enough to allow intraosseous support from the device with an adjacent stable cortex of cortical bone. TriMed buttress pins are used with washers and 2.4mm threaded pegs and 2.4mm screws.

All TriMed Wrist Fixation System implants are made from 316L Stainless Steel per ASTM F138/139 and are supplied non-sterile.

Indications for Use

TriMed Volar Plates and Radial Peg Plates
The following fracture configurations may be applicable for treatment using the TriMed Volar Plates and Radial Peg Plates:
1. Fractures, non-unions or osteotomies of the distal radius.

TriMed Ulnar Peg Plates
Fractures, non-unions and osteotomies of the distal end of the ulna.

TriMed Pin Plates
The following fracture configurations may be applicable for treatment using the TriMed Pin Plates:
1. Fractures of the radial column of the wrist.
2. Fractures of the dorsal ulnar cortex of the distal radius

TriMed Wire Forms and Hook Plates
Fragments of the distal radius large enough to allow intraosseous support from the device with an adjacent stable cortex of cortical bone.

Technological Characteristics

The subject TriMed Wrist Fixation System Devices are similar to the predicate devices in material, size, packaging, sterility, and has similar indications for use.

Substantial Equivalence: - Non-Clinical Evidence Performance Data

TriMed Wrist Fixation System 3 Implants were evaluated for following:

- Construct Cyclic endurance (Volar and Peg Plates) to predicates
- Construct Static load displacement (Volar and Peg Plates) to predicates
- 4-point bending (Longest Volar Plate) were conducted according to ASTM F382, and results were compared to the acceptance criteria listed in FDA guidance document, "Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway"
- Engineering analysis to predicates (Hook Plates, Pin Plates and Buttress Pins)
- Cytotoxicity, Sensitization and Irritation testing in accordance with ISO 10993-1:2018 (All implants)
- All system screws were tested per ASTM F543-17 for:
    - Torsional Strength
    - Driving Torque
    - Axial Pullout Strength Calculation
    - Results were compared to the acceptance criteria listed in FDA guidance document "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway "

Substantial Equivalence: - Clinical Evidence

Clinical testing was not necessary for the determination of substantial equivalence.

Substantial Equivalence – Conclusions

TriMed Wrist Fixation System 3 devices are substantially equivalent to the predicate devices in which basic design features, intended uses, indications for use, manufacturing, packaging, and labeling are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness.

The submitted mechanical testing data and engineering analyses show the subject devices are substantially equivalent to that of the predicate devices for the desired indications.

Based on the indications for use, technological characteristics, and the summary of data submitted, TriMed Inc. has determined that the proposed devices are substantially equivalent to the currently marketed predicate device.