January 15, 2025

TriMed, Inc.
Divya Raghavi Nandakumar
Regulatory Affairs Supervisor
27533 Avenue Hopkins
Santa Clarita, California 91355

Re: K243569
Trade/Device Name: TriMed Wrist Fixation System (Volar Bearing Plates); TriMed Wrist Fixation System (Volar Fixed Angle Plates); TriMed Wrist Fixation System (Hook Plates); TriMed Wrist Fixation System (Pin Plates); TriMed Wrist Fixation System (Peg Plates); TriMed Wrist Fixation System (Shear Plates); TriMed Wrist Fixation System (Wireform plates and Washer); TriMed Wrist Fixation System (Wireforms); TriMed Wrist Fixation System (Torx Cortical Screws); TriMed Wrist Fixation System (Torx Threaded Pegs); TriMed Wrist Fixation System (Torx Unthreaded Pegs); TriMed Wrist Fixation System (Hex Cortical Screw 3.2mm); TriMed Radial Osteotomy System (Radial Osteotomy Plates); TriMed Radial Osteotomy System (Torx Smooth Pegs 1.8mm); TriMed Wrist Fixation System 3 (Welded Wireforms)
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, NDG, NDL
Dated: November 1, 2024
Received: November 18, 2024

Dear Divya Raghavi Nandakumar:

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 Ferriera, 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)*

K243569

Device Name

TriMed Wrist Fixation System (Volar Bearing Plates);
TriMed Wrist Fixation System (Volar Fixed Angle Plates);
TriMed Wrist Fixation System (Hook Plates);
TriMed Wrist Fixation System (Pin Plates);
TriMed Wrist Fixation System (Peg Plates);
TriMed Wrist Fixation System (Shear Plates);
TriMed Wrist Fixation System (Wireform plates and Washer);
TriMed Wrist Fixation System (Wireforms);
TriMed Wrist Fixation System (Torx Cortical Screws);
TriMed Wrist Fixation System (Torx Threaded Pegs);
TriMed Wrist Fixation System (Torx Unthreaded Pegs);
TriMed Wrist Fixation System (Hex Cortical Screw 3.2mm);
TriMed Radial Osteotomy System (Radial Osteotomy Plates);
TriMed Radial Osteotomy System (Torx Smooth Pegs 1.8mm);
TriMed Wrist Fixation System 3 (Welded Wireforms)

Indications for Use *(Describe)*

Specific indications for use of the subject devices in Wrist Fixation System are as follows:
TriMed Volar Plates and Radial Peg Plates:
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:
1. Fractures of the radial column of the wrist.
2. Fractures of the dorsal ulnar cortex of the distal radius.

TriMed Wire Forms, Shear Plates 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.

TriMed Radial Osteotomy System is indicated for osteotomies of the distal radius.

TriMed Welded Wire Forms in Wrist Fixation System 3 is indicated for 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.

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

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510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information — 21 CFR 807.92(a)(1)

Submitter: TriMed, Inc.
27533 Avenue Hopkins
Santa Clarita, CA 91355
USA Phone: 1-661-255-7406
Establishment Registration Number: 2031009

Contact Person: Divya Raghavi Nandakumar
Regulatory Affairs Supervisor
Phone: 1-661-255-7406
Email: divyarnandakumar@trimedortho.com

Device Information — 21 CFR 807.92(a)(2)

Trade Name: TriMed Wrist Fixation System (Volar Bearing Plates);
TriMed Wrist Fixation System (Volar Fixed Angle Plates);
TriMed Wrist Fixation System (Hook Plates);
TriMed Wrist Fixation System (Pin Plates);
TriMed Wrist Fixation System (Peg Plates);
TriMed Wrist Fixation System (Shear Plates);
TriMed Wrist Fixation System (Wireform plates and Washer);
TriMed Wrist Fixation System (Wireforms);
TriMed Wrist Fixation System (Torx Cortical Screws);
TriMed Wrist Fixation System (Torx Threaded Pegs);
TriMed Wrist Fixation System (Torx Unthreaded Pegs);
TriMed Wrist Fixation System (Hex Cortical Screw 3.2mm);
TriMed Radial Osteotomy System (Radial Osteotomy Plates);
TriMed Radial Osteotomy System (Torx Smooth Pegs 1.8mm);
TriMed Wrist Fixation System 3 (Welded Wireforms)

Name: Plate, Fixation, Bone (primary)
Screw, Fixation, Bone
Pin, Fixation, Smooth
Washer, Bolt, Nut, Non-Spinal Metallic

Number: 21 CFR 888.3030

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Regulation Name: Single/multiple component metallic bone fixation appliances and accessories (primary)
Smooth or threaded metallic bone fixation fastener
Classification: Class II
Product Code: HRS, HWC, NDG, NDL
Review Panel: Orthopedic

Legally Marketed Predicate Device(s) 21 CFR 807.92(a)(3)

Device Trade Name: TriMed Wrist Fixation System 3
510(k) Number: K222637
Product Code: HRS

Device Description 21 CFR 807.92(a)(4)

TriMed Volar Bearing Plates and Volar Fixed Angle Plates consist of anatomically shaped plates used for fractures, non-unions or osteotomies of the distal radius. Volar Bearing Plates utilize distal bearings to allow peg angulation. Volar Fixed Angle Plates have pre-defined peg-hole trajectories. TriMed Fixed Angle and Bearing Plates are compatible with 2.3mm locking pegs and 2.3mm 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 2.3mm 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 2.3mm screws.

TriMed Radial Peg Plates are anatomically shaped for the radial column used for fractures, nonunions or osteotomies of the distal radius. TriMed Radial Peg Plates are compatible with 2.3mm 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 2.3mm screws and locking pegs.

TriMed Shear Plates are anatomically shaped plates used for fragments of the distal radius. TriMed Shear Plates are compatible with 2.3mm screws.

TriMed Wire Forms 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 Wire Forms are used with washers or wireform plates and 2.3mm threaded pegs and 2.3mm screws. TriMed Welded Wireforms have a welded washer that accept 2.3mm screws.

TriMed Radial Osteotomy Plates are used to perform osteotomies of the distal radius. TriMed Radial Osteotomy Plates have pre-defined peg-hole trajectories. TriMed Radial Osteotomy Plates are compatible with 2.3mm locking pegs and 2.3mm non-locking cortical bone screws distally and 3.2mm screws proximally.

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

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Intended Use / Indications for Use	21 CFR 807.92(a)(5)

Specific indications for use of the subject devices in Wrist Fixation System are as follows:
TriMed Volar Plates and Radial Peg Plates:
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:
1. Fractures of the radial column of the wrist.
2. Fractures of the dorsal ulnar cortex of the distal radius.
TriMed Wire Forms, Shear Plates 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.

TriMed Radial Osteotomy System is indicated for osteotomies of the distal radius.

TriMed Welded Wire Forms in Wrist Fixation System 3 is indicated for Fragments of the distal radius large enough to allow intraosseous support from the device with an adjacent stable cortex of cortical bone.

Indications for Use Comparison	21 CFR 807.92(a)(5)

Devices included in this 510(k) premarket notification have identical indications to indications for a subset of devices in the predicate 510(k) - K222637.

Comparison of Technological Characteristics	21 CFR 807.92(a)(6)

TriMed devices included in this 510(k) premarket notification are substantially equivalent to the predicate - TriMed Wrist Fixation System 3, in terms of material, design features, principles of operation, manufacturing, packaging, and labeling. Any differences between the proposed device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness.

Performance Data	21 CFR 807.92(b)

TriMed devices included in this 510(k) premarket notification and Predicate devices (Wrist Fixation System 3 cleared under K222637) assessed to identify worst-case representative devices. Worst-case representative devices were subjected to performance testing. This assessment is documented in QR-2738 Design Verification for WS3, WFS, and ROS. In some cases, the worst-case representative devices identified were in fact the predicate devices previously cleared under K222637. The performance test reports for these devices are provided once again for FDA review.

TriMed Welded Buttress Pins exhibited superior performance when compared to a predicate device

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(buttress pins in Wrist Fixation System 3 cleared under K222637) during static and endurance testing when compared to a predicate device.

TriMed screws included in this premarket notification were tested per the recommendations cited in the FDA Guidance Document, Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway. Refer to TRL-69, Test Report for Static Testing of TriMed Bone Screws – 2.3mm, 2.7mm, 3.2mm.

Clinical studies were not conducted for the subject devices.