March 19, 2025

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

Re: K243999
Trade/Device Name: TriMed Ankle Fixation System
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: December 24, 2024
Received: December 26, 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP) titled "K243999 – Predetermined Change Control Plan – AFS 10MAR2025.pdf". Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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)*

K243999

Device Name

TriMed Ankle Fixation System

Indications for Use *(Describe)*

The TriMed Sidewinder and Cluster Plates are indicated for fractures, non-unions & osteotomies of the distal fibula.

The TriMed Straight Plates and Ankle Hook Plates are indicated for fractures, non-unions & osteotomies of the distal fibula and distal tibia.

The TriMed Medial Malleolar Sleds and 4.0 Cannulated Compression Screws are indicated for fractures, non-unions & osteotomies of the Medial Malleolus of the distal tibia.

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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K243999

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

Date Prepared: March 14, 2025

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

Trade Name:	TriMed® Ankle Fixation System
Common Name:	Ankle Plating System
Regulation Number:	21 CFR 888.3030
Regulation Name:	Single/multiple component metallic bone fixation appliances and accessories.
Classification:	Class II
Product Code:	HRS, HWC, NDL, NDG
Review Panel:	Orthopedic

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

Primary Predicate: K060041 – TriMed Bone Plates (21 CFR 888.3030; HRS; Class II)

Additional Predicate(s): K010545 – Tension Band Wire (21 CFR 888.3040; NDL; Class II)
K143385 – Acumed Ankle Plating System (21 CFR 888.3030; HRS; Class II)

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Device Description 21 CFR 807.92(a)(4)

TriMed Ankle Fixation System (AFS) is a comprehensive ankle fracture fixation system intended to aid the treatment of certain types of fractures, malunions, and non-union of the tibia and fibula. The system is designed to constraint movement between bone surfaces and is intended only as an aid to fix the fracture in place during the healing process.

The system implants consist of plates, screws and wire form devices and supporting instrumentation. The implants vary in designs, and sizes to accommodate patient size, anatomy and fracture type. The implants manufactured from 316L medical grade stainless steel per ASTM F138 or F139.

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

The TriMed Sidewinder and Cluster Plates are indicated for fractures, non-unions & osteotomies of the distal fibula.

The TriMed Straight Plates and Ankle Hook Plates are indicated for fractures, non-unions & osteotomies of the distal fibula and distal tibia.

The TriMed Medial Malleolar Sleds and 4.0 Cannulated Compression Screws are indicated for fractures, non-unions & osteotomies of the Medial Malleolus of the distal tibia.

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

The TriMed Ankle Fixation System has the basic design features and intended use as the predicate device. Any differences between them are considered minor and do not raise questions concerning safety or effectiveness. Based on the information provided, TriMed has determined that the proposed device is substantially equivalent to the predicate device.

Non-Clinical Summary & Conclusions 21 CFR 807.92(b)

Mechanical performance of the TriMed Ankle Fixation System was established in accordance with the below standards/guidance in comparison to the predicate device.

- ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws.
- FDA Guidance, Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway.
- ASTM F382, Standard Specification and Test Method for Metallic Bone Plates.

The TriMed Ankle Fixation System performed equivalent or better in comparison to the predicate device.

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Conclusion

Substantial equivalence of the subject TriMed Ankle Fixation to the predicate TriMed Bone Plate devices is based on the following:

- Both devices have the same intended use.
- Both devices have the same fundamental scientific technology and principles of operation.
- Both devices share similar functional and technological characteristics.

Evaluation of the associated risks do not raise different questions of safety or effectiveness. Performance data referenced in this 510(k) submission demonstrates that the subject TriMed Ankle Fixation System is safe and effective for its intended use and is substantially equivalent to the predicate device.

Predetermined Change Control Plan (PCCP)

This submission includes a Predetermined Change Control Plan (PCCP) for TriMed Ankle Fixation System, Medial Malleolar Sled and Washer components. The PCCP establishes a comprehensive framework for managing a pre-planned modification, which includes releasing a design that combines the Medial Malleolar Sled and Washer into a single device. It also details the methods for implementing these modifications. A summary of the proposed modifications, testing methods, validation activities, and user communication is provided in the table below.

Planned Modifications	**Test Methods and Validation Activities**	**Communication to Users, as Needed**
Combine the Medial Malleolar Sled and Washer devices into a single device.	Biocompatibility and Sterilization will be conducted to the same requirements as set for the TriMed Ankle Fixation System Construct Static bend and endurance bend testing (per Medial Malleolar Sled Static and Endurance Test Plan Rev 1.0) will be performed to verify the mechanical performance for fracture fixation.	Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device material composition.