May 22, 2025

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

Re: K250935
Trade/Device Name: TriMed Fifth Metatarsal System (Fifth Metatarsal Plate); TriMed Fifth Metatarsal System (Fifth Metatarsal Screw)
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
Dated: March 28, 2025
Received: March 28, 2025

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 (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)*

K250935

Device Name

TriMed Fifth Metatarsal System (Fifth Metatarsal Plate);
TriMed Fifth Metatarsal System (Fifth Metatarsal Screw)

Indications for Use *(Describe)*

The TriMed Fifth Metatarsal System is indicated for use in stabilization of fractures, malunions and non-unions of the fifth metatarsal.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K250935

510(k) Summary

Prepared on: 2025-03-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	TriMed, Inc.
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Correspondent Contact Telephone	(574) 377-0111
Correspondent Contact	Mr. David Anderson
Correspondent Contact Email	david.anderson@tech2medllc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TriMed Fifth Metatarsal System (Fifth Metatarsal Plate); TriMed Fifth Metatarsal System (Fifth Metatarsal Screw)
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K072740	Mondeal Extremity Bone Fixation System	HRS
K181820	Medline Unite Mini Plates and Screws	HRS
K133451	Stryker Fixos Screw System	HWC

Device Description Summary

21 CFR 807.92(a)(4)

The TriMed Fifth Metatarsal System implants are non-sterile, non-bioabsorbable implantable devices used as aids to the treatment of certain types of fractures and non-unions that lend themselves to the principle of plate and/or screw fixation. The TriMed Fifth Metatarsal System consists of fixation plates and screws as well as stand-alone screws.

The TriMed Fifth Metatarsal System implants are made from implant grade stainless steel.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The TriMed Fifth Metatarsal System is indicated for use in stabilization of fractures, malunions and non-unions of the fifth metatarsal.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Subject device's Indications for Use are similar to the listed predicates.

Technological Comparison

21 CFR 807.92(a)(6)

TriMed devices included in this 510(k) submission are substantially equivalent to the predicate devices 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.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Plates:
Subject device plates and predicate device plates were subject to static cantilever loading, simulating biomechanical conditions. Testing showed the subject devices were able to resist higher peak loads than the tested predicate devices. In addition, the subject devices were fatigue tested to 150,000 cycles. All subject plates passed and met all acceptance criteria.

Screws:
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. All subject screws passed and met all acceptance criteria.

Clinical studies were not conducted for the subject devices.

Based on performance testing, TriMed Inc. has determined that the proposed subject devices are substantially equivalent to the currently marketed predicate device.