



November 26, 2024

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

Re: K243050

Trade/Device Name: TriMed Posterior Malleolus 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
Dated: September 27, 2024
Received: September 27, 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 Ferreira, MS
Assistant Director, Biomedical Engineer
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

Indications for Use

Submission Number (if known)

K243050

Device Name

TriMed Posterior Malleolus Fixation System

Indications for Use (Describe)

TriMed Posterior Malleolus Fixation System is indicated for fractures, osteotomies, and non-unions 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.

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	TriMed, Inc.
Applicant Address	27533 Avenue Hopkins Santa Clarita CA 91355 United States
Applicant Contact Telephone	6612557406
Applicant Contact	Mrs. Divya Raghavi Nandakumar
Applicant Contact Email	divyarnandakumar@trimedortho.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	TriMed Posterior Malleolus Fixation System
Common Name	Plate, Fixation, Bone (primary) Screw, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories (primary) Smooth or threaded metallic bone fixation fastener
Regulation Number	888.3030 (primary), 888.3040
Product Code(s)	HRS (primary), HWC

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K080522	Synthes 3.5mm LCP Distal Tibia T Plates	HRS

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

TriMed Posterior Malleolus Fixation System is indicated for fractures, osteotomies, and non-unions of the distal tibia. TriMed Posterior Malleolus Fixation System plates and screws are manufactured from medical grade stainless steel. Posterior Malleolar L-Plates and T-Plates accept 2.7mm and 3.2mm locking and non-locking screws.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

TriMed Posterior Malleolus Fixation System is indicated for fractures, osteotomies, and non-unions of the distal tibia.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

Both TriMed Posterior Malleolus Fixation system and the predicate device are indicated for treatment of fractures, osteotomies and non-unions in the distal tibia. The predicate's indications for use statement highlights "osteopenic bone". Difference between the two indications for use statements is very minor. The difference does not constitute a new intended use.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

TriMed Posterior Malleolus Fixation System is substantially equivalent to Synthes 3.5mm LCP Distal Tibia T Plates (predicate) 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\(b\)](#)

TriMed Posterior Malleolus Plates and Predicate plates (Synthes Distal Tibia T-Plates) were subjected to static and endurance testing. TriMed Posterior Malleolar plates exhibited superior performance when compared to a predicate device (Synthes Distal Tibia T-Plates) during static testing when compared to a predicate device.

TriMed Posterior Malleolus Fixation System screws 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.

Clinical studies were not conducted for the subject devices.

Based on the indications for use, technological characteristics, and the summary of data submitted, TriMed Inc. has determined that TriMed Malleolus Fixation System devices are substantially equivalent to the predicate device (Synthes 3.5mm LCP Distal Tibia T Plates) cleared under K080522.