August 20, 2025

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

Re: K252061
Trade/Device Name: Distal Xtremities 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: June 30, 2025
Received: July 1, 2025

Dear Kelli 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 Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252061

Please provide the device trade name(s).

Distal Xtremities System

Please provide your Indications for Use below.

The TriMed Distal Xtremities System is indicated for use in stabilization of fractures, malunions and non-unions of the small bones of the foot.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252061

510(k) Summary

Prepared on: 2025-06-30

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	(979)204-4952
Applicant Contact	Mr. Blesson Abraham
Applicant Contact Email	Blesson.Abraham@henryschein.com
Correspondent Name	Tech2Med, LLC
Correspondent Address	6450 Old Darby Trl NE Ada MI 49301 United States
Correspondent Contact Telephone	(574)527-9214
Correspondent Contact	Mrs. Kelli Anderson
Correspondent Contact Email	kelli.anderson@tech2md.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Distal Xtremities System
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
K050681	Easy Lock Osteosystem with Xtremities Plates	HRS
K050681	Easy Lock Osteosystem with Xtremities Plates	HWC

Device Description Summary

21 CFR 807.92(a)(4)

The TriMed Distal Xtremities System includes 2.0mm and 2.3mm locking screws and six new plate configurations designed for distal extremity fixation. The titanium plates vary in hole count and geometric profile (straight and T-shaped) to accommodate a range of anatomical and clinical needs. The Distal Xtremities plates represent variations in design to TriMed's current Xtremities plate, with additional sizes and removal of the PEEK inserts.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The TriMed Distal Xtremities System is indicated for use in stabilization of fractures, malunions and non-unions of the small bones of the foot.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Distal Xtremities System indication is a more narrow indication within the cleared Easy Lock and Xtremities System indications. The Distal Xtremities System focuses on the stabilization of the small bones of the foot.

Technological Comparison

21 CFR 807.92(a)(6)

Both the predicate and the Distal Xtremities System use similarly designed plates and screws to achieve stabilization and fixation of small bones as an aid to healing. While the predicate utilizes titanium alloy and PEEK as implant materials, the Distal Xtremities System is made entirely of titanium alloy. FEA analysis was used to show that design differences (number of screw holes, plate thickness, plate lengths) and material differences did not have a negative impact on mechanical strength of the DXS plates. Performance characteristics of the Distal Xtremities System screws were evaluated against predicate TriMed screws used for stabilization of small bones in the foot.

Implant and manufacturing materials used in the Distal Xtremities System are identical to those used in previously cleared TriMed implant products. Biocompatibility analysis of these materials have been reviewed by the FDA.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Subject device screws were evaluated against TriMed predicate screws for performance and found to be substantially equivalent. Analysis included theoretical calculations along with retrospective review of physical testing data to show that the new 2.0 and 2.3mm screws did not create a new worst case within the TriMed screw families. Therefore physical testing of the new screws was not necessary.

FEA analysis was completed comparing material performance between the new Distal Xtremities plates and the current Easy Lock and Xtremities plates. The analysis showed that the dimensional differences and the change in plate materials does not impact performance.

N/A

Engineering analysis and physical test data show that the Distal Xtremities Screws are substantially equivalent to other TriMed screws used in the fixation of small bones of the foot. FEA analysis comparing the Distal Xtremities Plates to the predicates, showed that the dimensional and material changes did not impact mechanical performance.