March 19, 2025

TriMed, Inc.
Mikayla German
Regulatory Affairs Sr. Specialist
275333 Avenue Hopkins
Santa Clarita, California 91355

Re: K243987
Trade/Device Name: TriMed Elbow and Forearm 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, NDL, NDG, HWC
Dated: December 10, 2024
Received: December 23, 2024

Dear Mikayla German:

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 “K243987 – Predetermined Change Control Plan – EFS_14MAR2025”. 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)*

K243987

Device Name

TriMed Elbow and Forearm System

Indications for Use *(Describe)*

The following fracture configurations may be applicable for treatment using TriMed Elbow and Forearm System:
1. Fractures, malunions and non-unions of the radius and ulna amenable to plate and/or screw fixation where the size, shape and location of the fractured bone are appropriate for the specific implant(s) used.
2. Fractures and osteotomies of the olecranon.

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) #: K243987

510(k) Summary

Prepared on: 2025-03-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	TriMed, Inc.
Applicant Address	275333 Avenue Hopkins Santa Clarita CA 91355 United States
Applicant Contact Telephone	574-767-6560
Applicant Contact	Ms. Mikayla German
Applicant Contact Email	mikayla.german@henryschein.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TriMed Elbow and Forearm 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, NDL, NDG, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K060041	TriMed Bone Plates	HRS
K010545	Tension Band Wire	NDL

Device Description Summary

21 CFR 807.92(a)(4)

The TriMed® Elbow and Forearm System, comprising of bone plates, wire forms and screws, are intended to be used as an aid to the treatment of certain types of fractures and osteotomies that lend themselves to the principle of plate and/or screw, wire form, tension band, or pin fixation. The TriMed Elbow and Forearm System plates, wire forms and screws are designed to provide additional constraint of movement of a fractured fused or osteotomized bone and are intended only as an aid to fix the fracture in place during the healing process.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The following fracture configurations may be applicable for treatment using TriMed Elbow and Forearm System:
1. Fractures, malunions and non-unions of the radius and ulna amenable to plate and/or screw fixation where the size, shape and location of the fractured bone are appropriate for the specific implant(s) used.
2. Fractures and osteotomies of the olecranon.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The TriMed Elbow and Forearm System has a similar, but if not same, indications for use as the referenced predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The implants within the TriMed Elbow and Forearm System (Plates, Wireforms, Washer, and Cortical Screws) and the predicate devices are manufactured from 316L Stainless Steel. The TriMed Elbow and Fixation System is substantially equivalent to the predicate devices in terms of design features, principles of operation, manufacturing, packaging, and labeling. Any differences between the proposed devices and the predicate devices 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 Elbow and Forearm System 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: Guidance for Industry and Food and Drug Administration Staff.
Static and dynamic four-point bending were conducted per ASTM F382-17.

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 the proposed devices (Bridge plates, 2.7mm locking and non-locking screws) are substantially equivalent to the currently marketed predicate device.

K243987 - Predetermined Change Control Plan (PCCP) overview is provided below
This submission includes a Predetermined Change Control Plan (PCCP) for TriMed Elbow Forearm System, Olecranon Sled and Washer components. The PCCP establishes a comprehensive framework for managing a pre-planned modification, which includes releasing a design that combines the Olecranon 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 - Combine the Olecranon Sled and Washer devices into a single device.

Test Methods and Validation Activities - Biocompatibility and Sterilization will be conducted to the same requirements as set for the TriMed Elbow Forearm System. Construct static bend and endurance bend testing will be performed to verify the mechanical performance for fracture fixation per K243987-Predetermined Change Control Plan-EFS_14MAR2025.

Communication to Users, as Needed - Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device material composition.