January 15, 2026

TriMed, Inc.
Sneha Potlapally
Senior Regulatory Affairs Specialist
27533 Ave. Hopkins
Santa Clarita, California 91355

Re: K254002
Trade/Device Name: TriMed Volar Bearing Plates (VBEAL-13-7S); TriMed Volar Bearing Plates (VBEAR-13-7S); TriMed Volar Bearing Plates (VBEAL-14-7S); TriMed Volar Bearing Plates (VBEAR-14-7S); TriMed Volar Bearing Plates (VBEAL-16-7S); TriMed Volar Bearing Plates (VBEAR-16-7S)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: December 9, 2025
Received: December 15, 2025

Dear Sneha Potlapally:

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,

Thomas Mcnamara -S

For: 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.	K254002

Please provide the device trade name(s).

TriMed Volar Bearing Plates (VBEAL-13-7S);
TriMed Volar Bearing Plates (VBEAR-13-7S);
TriMed Volar Bearing Plates (VBEAL-14-7S);
TriMed Volar Bearing Plates (VBEAR-14-7S);
TriMed Volar Bearing Plates (VBEAL-16-7S);
TriMed Volar Bearing Plates (VBEAR-16-7S)

Please provide your Indications for Use below.

The TriMed Volar Plates are intended to be used as an aid to the treatment of certain types of fractures, non-unions or osteotomies that lend themselves to the principle of plate and screw fixation.

The following fracture configurations may be applicable for treatment using TriMed Volar Plates:
1. Fractures, non-unions or osteotomies of the radius

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K254002

510(k) Summary

Prepared on: 2026-01-14

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	Ms. Sneha Potlapally
Applicant Contact Email	snehapotlapally@trimedortho.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TriMed Volar Bearing Plates (VBEAL-13-7S); TriMed Volar Bearing Plates (VBEAR-13-7S); TriMed Volar Bearing Plates (VBEAL-14-7S); TriMed Volar Bearing Plates (VBEAR-14-7S); TriMed Volar Bearing Plates (VBEAL-16-7S); TriMed Volar Bearing Plates (VBEAR-16-7S)
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222637	TriMed Wrist Fixation System 3	HRS

Device Description Summary

21 CFR 807.92(a)(4)

TriMed Volar Bearing Plates are intended to be used as an aid to the treatment of certain types for fractures, non-unions and osteotomies of the radius. Like every type of orthopaedic implant, these implants cannot be assumed to be uniformly effective without risk. Use of these implants is not a substitute for normal tissue healing. The TriMed Volar Plates are designed to provide additional constraint of movement of a fractured/osteotomized bone and are intended only as an aid to fix the injury in place during the healing process. These plates are made from 316L Stainless Steel per ASTM F138/F139. The new plates will be offered as part of TriMed Wrist Fixation system 3 (received FDA clearance under K222637) . They will be made available in 3 sizes (13, 14 &16 holes) for left and right each.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The TriMed Volar Plates are intended to be used as an aid to the treatment of certain types of fractures, non-unions or osteotomies that lend themselves to the principle of plate and screw fixation.

The following fracture configurations may be applicable for treatment using TriMed Volar Plates:
1. Fractures, non-unions or osteotomies of the radius

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device's Indications for Use is similar to the predicate device. Performance testing was conducted to evaluate the devices included in this submission. Modified indications for use statement does not affect the safety and effectiveness of the device when used as labeled

Technological Comparison

21 CFR 807.92(a)(6)

TriMed subject device (Volar Bearing Plates) included in this 510(k) submission is substantially equivalent to the predicate device in TriMed Wrist Fixation System 3 (previously cleared under K222637), in terms of material, design features, principle of operation, manufacturing, packaging and labeling. Any differences between the proposed device and the predicate device are considered minor and do not raise questions concerning safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

TriMed Long Volar Plates included in this application were tested per the recommendations cited in the FDA Guidance Document, FDA-2022-D-0552 - Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway. Clinical testing was not necessary for the determination of substantial equivalence.TriMed Long Volar Plates, surgical instrument, and caddy design do not adversely affect product performance, cleanability, and sterilization and therefore do not raise any new concerns of safety and efficacy. The similar technological characteristics, indications for use and performance testing support the substantial equivalence of the Threaded Long Volar Plates with the predicate devices.