April 8, 2025

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

Re: K250948
Trade/Device Name: TriMed Fusion Cup 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: March 28, 2025
Received: March 21, 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,

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

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)*

K250948

Device Name

TriMed Fusion Cup System

Indications for Use *(Describe)*

The following are osteosynthesis configurations that may be applicable to the TriMed Fusion Cups and Screws:
1. Arthrodesis of joints in the midfoot
2. Arthrodesis of the wrist and hand

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) #: K250948

510(k) Summary

Prepared on: 2025-04-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	TriMed, Inc.
Applicant Address	27533 Avenue Hopkins Santa Clarita CA 91355 United States
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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@tech2medllc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TriMed Fusion Cup 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, HWC

Device Description Summary

21 CFR 807.92(a)(4)

The TriMed Fusion Cup System is used as an aid to the treatment of certain types of small bone arthrodesis. Fusion cups are manufactured from implantable medical grade polyetheretherketone (PEEK) and allow polyaxial locking of screws. The cups are designed to be used with TriMed 2.4mm compression screws made of Ti6Al-4V ELI. Variation in implant size, diameter, and shape are intended to allow the implants to accommodate differences in patient size and sites of application. This special 510(k) is submitted to allow market release of additional sizes of fusion cups and compression screws.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The following are osteosynthesis configurations that may be applicable to the TriMed Fusion Cups and Screws:
1. Arthrodesis of joints in the midfoot
2. Arthrodesis of the wrist and hand

Indications for Use Comparison

21 CFR 807.92(a)(5)

The original indication for use cleared under K050681 stated that the Fusion Cup System (EasyLock Osteosystem with Xtremities Plates) may be used for permanent or temporary osteosynthesis of small bones, tarsal and carpal fractures, and for the fixation of osteotomies or arthrodesis. Current labeling for the TriMed Fusion Cup System defines the indications for use for arthrodesis of joints in the midfoot, and arthrodesis of the wrist and hand. The revised, more specific indication for use falls within the K050681 cleared indication. Following FDA Guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device," no submission is necessary for limiting the indication to one within the already cleared indications for use. The change does not describe a new disease, condition, or patient population, it does not introduce new risks or significantly modify existing risks and the surgical technique did not change. The FDA Guidance and "Guidance for Industry: General/Specific Intended Use" was also reviewed and taken into consideration regarding the narrowing of the indications for use statement.

Technological Comparison

21 CFR 807.92(a)(6)

The new TriMed Fusion Cups and Compression Screws utilize a similar design philosophy offering additional size configurations from the original clearance. They are made of the same materials as the predicate devices and have the same principle of operation. Design control activities including performance testing following FDA Guidance and product evaluation prove that the design changes do not impact safety and efficacy, nor do they introduce new risks. The subject system is a line extension that contains larger diameter screws, PEEK cups that contain different numbers or screw holes, and a new smaller diameter PEEK cup.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The new Fusion Cup designs successfully passed verification testing following the same protocol executed on the original device. The new screws successfully met performance requirements defined within the FDA Guidance, "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway." Static and endurance construct compression testing was performed on the PEEK cups and ASTM F543 testing was performed on the screws.