April 10, 2025

TriMed, Inc.
Thomas Arnold
Sr. Regulatory Affairs Specialist
27533 Avenue Hopkins
Santa Clarita, California 91355

Re: K243943
Trade/Device Name: TriMed® Compression Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 20, 2024
Received: December 20, 2024

Dear Thomas Arnold:

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). 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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.

510(k) Number *(if known)*
K243943

Device Name
TriMed® Compression Screws

Indications for Use *(Describe)*
The TriMed® Small Compression Screws are indicated for fracture fixations, non-unions, and osteotomies of small bones and small bone fragments in the hand, wrist, elbow, ankle, and foot.

The TriMed® Large Compression Screws are indicated for fracture fixations, non-unions, and osteotomies of large bones and large bone fragments in the hand, wrist, elbow, ankle, and foot.

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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510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information — 21 CFR 807.92(a)(1)

Submitter:	TriMed, Inc. 27533 Avenue Hopkins Santa Clarita, CA 91355 USA Phone: 1-661-255-7406 Establishment Registration Number: 2031009
Contact Person:	Thomas Arnold Sr. Regulatory Affairs Specialist Phone: 1-661-255-7406 Email: thomas.arnold@henryschein.com
Date Prepared:	December 20, 2024

Device Information — 21 CFR 807.92(a)(2)

Trade Name:	TriMed® Compression Screws
Common Name:	Screw, Fixation, Bone
Regulation Number:	21 CFR 888.3040
Regulation Name:	Smooth or threaded metallic bone fixation fastener
Classification:	Class II
Product Code:	HWC
Review Panel:	Orthopedic

Legally Marketed Predicate Device(s) — 21 CFR 807.92(a)(3)

Device Trade Name:	Omnitech Large, TriMed Compression Screw
510(k) Number:	K093676 (Primary Predicate)
Product Code:	HWC, HTY
Device Trade Name:	Omnitech System & Easy Lock Osteosystem with Xtremities Plates
510(k) Number:	K050681 (Secondary Predicate)
Product Code:	HWC, HRS

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Device Trade Name:	DePuy Synthes 4.0 mm and 4.5 mm Cortex Screws, DePuy Synthes 2.4 mm Cannulated Screws, DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws, DePuy Synthes 4.5 Cannulated Screws, DePuy Synthes 6.5 mm Cannulated Screws, DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws, DePuy Synthes 1.5 mm Headless Compression Screws, DePuy Synthes 2.4 mm Headless Compression Screws, DePuy Synthes 3.0 mm Headless Compression Screws, DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screw
510(k) Number:	K161616 (Secondary Predicate)
Product Code:	HWC

Device Description 21 CFR 807.92(a)(4)

TriMed Compression Screws consists of small and large cannulated compression screws made of medical grade stainless steel and titanium. The small screws are indicated to be used as an aid in fracture fixations, non-unions and osteotomies of small bones and small bone fragments; the large screws are indicated to be used in fracture fixations, non-unions and osteotomies of large bones and large bone fragments. The TriMed Compression Screws are designed to provide additional constraint of movement of a fractured/osteotomized bone and non-unions and are intended only as an aid to fix the fracture/osteotomy in place during the healing process.

Intended Use / Indications for Use 21 CFR 807.92(a)(5)

TriMed® Small Compression Screws are indicated for fracture fixations, non-unions, and osteotomies of small bones and small bone fragments in the hand, wrist, elbow, ankle, and foot.

TriMed® Large Compression Screws are indicated for fracture fixations, non-unions, and osteotomies of large bones and large bone fragments in the hand, wrist, elbow, ankle, and foot.

Comparison of Technological Characteristics 21 CFR 807.92(a)(6)

TriMed Compression Screws and the DePuy predicate devices are manufactured from stainless steel and titanium alloy, whereas the TriMed predicate devices are manufactured from titanium alloy only. The comparison to the secondary predicate, DePuy Synthes Compression Screws (K161616), supports the introduction of additional materials, as well as new screw diameters and lengths for the subject devices. TriMed Compression Screws are substantially equivalent to the predicate devices in terms of design features, principles of operation, manufacturing, packaging, and labeling. Any differences between the proposed device and the predicate devices are considered minor and do not raise different questions concerning safety or effectiveness.

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Performance Data 21 CFR 807.92(b)

Mechanical testing on TriMed Compression Screws was conducted in accordance with ASTM F543-17, FDA Guidance Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway, and/or in comparison to compression screws cleared under predicates K050681 and K093676.

Conclusion

Based on the indications for use, technological characteristics, and the summary of data submitted, TriMed, Inc. has determined that the subject device does not raise different questions of safety and effectiveness compared to the predicate devices. Therefore, the proposed subject device is substantially equivalent to the legally marketed predicate devices.

Predetermined Change Control Plan (PCCP)

This submission includes a Predetermined Change Control Plan (PCCP) for TriMed Compression Screws, prepared in alignment with the FDA draft guidance, "Predetermined Change Control Plans for Medical Devices." The PCCP establishes a comprehensive framework for managing pre-planned modifications, including introducing new material options, screw head designs, and a line extension featuring headed screws. It also details the methods for implementing these modifications while ensuring the TriMed Compression Screws remain as safe and effective as the predicate device. A summary of the proposed modifications, testing methods, validation activities, and user communication is provided in the table below.

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Planned Modifications	Test Methods and Validation Activities	Communication to Users, as Needed
Addition of materials (stainless steel and titanium alloy)	Testing for safety and effectiveness will be performed in accordance with ASTM F543-17 and/or directly against FDA-cleared predicates. Verification and validation will be conducted in accordance with the requirements outlined in the Modification Protocol. When applicable, test methods will follow the recommendations in the most recent version of the FDA guidance Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway.	Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device material composition.
Design change of screw head	Verification and validation will be conducted in accordance with the requirements outlined in the Modification Protocol, including adherence to IEC 62366-1. When applicable, test methods will follow the recommendations in the most recent version of the FDA guidance Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway.	N/A. Devices are distributed in system-specific trays. Appropriate drivers will be provided in these trays to facilitate implantation.
Line extension featuring large headed screws	Testing for safety and effectiveness will be performed in accordance with ASTM F543-17 and/or directly against FDA-cleared predicates. Verification and validation will be conducted in accordance with the	Line extension will be communicated by means of IFUs and Surgical Techniques.

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Planned Modifications	Test Methods and Validation Activities	Communication to Users, as Needed
	requirements outlined in the Modification Protocol. When applicable, test methods will follow the recommendations in the most recent version of the FDA guidance Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway.	