



August 12, 2026

TriMed, Inc.
Annika Lind
Senior Regulatory Affairs Specialist
27533 Avenue Hopkins
Santa Clarita, California 91355

Re: K262344

Trade/Device Name: Large 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: July 9, 2026
Received: July 10, 2026

Dear Annika Lind:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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.

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Please provide the device trade name(s).

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Large Compression Screws

Please provide your Indications for Use below.

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

Please select the types of uses.

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☐ Adults (22 years old and greater)

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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	(208) 586-0010
Applicant Contact	Ms. Annika Lind
Applicant Contact Email	ra@trimedortho.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Large Compression Screws
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Screw, Fixation, Bone
Regulation Number	888.3040
Product Code(s)	HWC

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K243943	TriMed Compression Screws	HWC

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The TriMed® Large Compression Screws are devices which are to be used as an aid to the treatment of certain types of fractures, non-unions and osteotomies that lend themselves to the principle of screw fixation. The TriMed Compression Screws are provided in sizes 4.5, 5.5, and 7.3mm headless (L) and self-drill cannulated (S) compression screws in lengths ranging from 26-128 mm, made of medical grade titanium.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The subject device's Indications for Use is similar to the predicate device(s). TriMed Compression Screws cleared under K243943 are indicated for fracture fixations, non-unions and osteotomies of large bones and large bone fragments in the hand, wrist, elbow, ankle, and foot. Subject devices included in this submission are also indicated for the exact same indications.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

TriMed subject device (S45A T, L45A T, S55A T, L55A T, S73A T, L73A T) included in this 510(k) application is substantially equivalent to the predicate device in TriMed Compression Screws (previously cleared under K243943), in terms of design, material, 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.

TriMed Large Compression screws included in this application were tested per TR-189 and has proved that the subject devices did not produce any unexpected issues of safety or effectiveness. The testing and analysis in TR-189 included theoretical Axial Pullout Strength (calculations per the Chapman Equation), Insertion and Removal Torque, and Torsional Strength per ASTM F543-23 and the recommendations cited in the FDA guidance document, "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway". Clinical testing was not necessary for the determination of substantial equivalence. TriMed Large Compression screws, surgical instruments, 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 Large Compression screws with the predicate device.