May 14, 2026

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

Re: K261241
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: April 15, 2026
Received: April 15, 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.	K261241

Please provide the device trade name(s).

TriMed Compression Screws

Please provide your Indications for Use below.

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

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)
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)

510(k) #: K261241

510(k) Summary

Prepared on: 2026-04-14

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	(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	TriMed 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 Compression Screws on this application consist of longer length 2.0 mm cannulated compression screws (lengths 25mm-40mm in 1mm increments) made of medical grade titanium. The 2.0mm diameter screws are indicated to be used as an aid in fracture fixations, non-unions and osteotomies of small bones and small bone fragments. The TriMed Compression Screws are designed to provide additional constraint of movement of a fractured/osteomized bone and non-unions and are intended only as an aid to fix the fracture/osteotomy in place during the healing process. TriMed, Inc. is expanding the L20 screw lengths and introducing a drop-in caddy (HCS-DCADDY) to expand the product offerings to address numerous feedback requests from the field. Additionally, as highlighted orange on the "Drawing for L20A Compression Screws", page 2, the tolerance for the major diameter went through a minor change from the originally submitted drawing under 510(k) K243943.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the TriMed Compression Screws on this application are substantially equivalent to the indications for use of the referenced predicate device(s). The subject and predicate TriMed Compression Screws cleared under K243943 are indicated for fracture fixations, non-unions, and osteotomies of small bones and small bone fragments in the hand, wrist, elbow, ankle, and foot.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate (K243943) TriMed Compression Screws subject devices are substantially equivalent in terms of design, principle of operation, material, manufacturing, packaging, and labeling. The predicate TriMed Compression Screws included 2.0 mm diameters and offered in lengths ranging from 8-24 mm (in 1 mm increments). The subject TriMed Compression Screws are offered in 2.0 mm diameters with additional lengths ranging from 25-40 mm (in 1 mm increments). 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)

Evaluation of mechanical performance (axial pullout, torsional yield strength, and insertion/removal torque) of the 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 the predicate device cleared under K243943. The biocompatiblity evaluation was based on identical materials and manufacturing compared to the predicate device. Implant configuration in the caddy were evaluated for adoption into the worst-case validated steam sterilization cycle. Assessments followed the same methods used to evaluate the predicate device.

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 device. Therefore, the proposed subject device is substantially equivalent to the legally marketed predicate devices.