January 18, 2024

TriMed, INC
% David Anderson
Regulatory Affairs Contractor
Tech2Med, LLC
6450 Old Darby TRL NE
Ada, Michigan 49301

Re: K234040
Trade/Device Name: TriMed Threaded Intramedullary Nail System
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, 2023
Received: December 21, 2023

Dear David 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.

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.

Submission Number *(if known)*

K234040

Device Name

TriMed Threaded Intramedullary Nail System

Indications for Use *(Describe)*

The TriMed Threaded IM Nail System is indicated for the treatment of select fractures and corrective osteotomies of short tubular bones.
Specific indications for TriMed Small Threaded IM Nails include:
1. Phalangeal fractures of the hand, non-unions, malunions and corrective osteotomies
2. Metacarpal fractures, non-unions, malunions and corrective osteotomies

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

Prepared on: 2024-01-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	TriMed, INC
Applicant Address	27533 Avenue Hopkins Valencia CA 91355 United States
Applicant Contact Telephone	(661) 255-7406
Applicant Contact	Mr. David Medoff
Applicant Contact Email	davidmedoff@trimedortho.com
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Correspondent Address	6450 Old Darby TRL NE Ada MI 49301 United States
Correspondent Contact Telephone	(574) 377-0111
Correspondent Contact	Mr. David Anderson
Correspondent Contact Email	david.anderson@tech2medllc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TriMed Threaded Intramedullary Nail System
Common Name	Screw, Fixation, Bone
Classification Name	Smooth or threaded metallic bone fixation fastener
Regulation Number	888.3040
Product Code	HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211783	TriMed Threaded Intramedullary Nail System	HWC
K230749	TriMed Threaded Intramedullary Nail System	HWC

Device Description Summary

21 CFR 807.92(a)(4)

TriMed Threaded Intramedullary (IM) Nail System implants are non-sterile, non-bioabsorbable implantable devices used as aids to the treatment of certain types of fractures and osteotomies that lend themselves to the principle of nail/rod/screw fixation. TriMed Threaded IM Nail System implants are cannulated, partially threaded, intramedullary fixation nails used to align and stabilize fractures and osteotomies of short tubular bones. TriMed threaded IM Nails are either made from Ti-6AL-4V ELI per ASTM F136 or 316L Stainless steel per ASTM F138. TriMed is adding 3.6mm Threaded IM Nails with length ranges between 30 and 70mm to the already cleared 1.8mm – 3.0mm diameter ranges

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The TriMed Threaded IM Nail System is indicated for the treatment of select fractures and corrective osteotomies of short tubular bones. Specific indications for TriMed Small Threaded IM Nails include:
1. Phalangeal fractures of the hand, non-unions, malunions and corrective osteotomies
2. Metacarpal fractures, non-unions, malunions and corrective osteotomies

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device's Indications for Use are identical to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject devices included in The TriMed Threaded IM Nail System are substantially equivalent to the predicate devices in which basic design features, manufacturing, packaging, and labeling are the same.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The TriMed Threaded IM Nail System implants were tested per the recommendations cited in the FDA Guidance Document, Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway, and per ASTM F543-17:
- Torsional Strength
- Driving Torque
- Axial Pullout Strength Calculation

Clinical testing was not necessary for the determination of substantial equivalence.

TriMed Threaded IM Nail System nails, surgical instrument, and tray designs 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 IM Nail System with the predicate devices.