August 6, 2021

TriMed, Inc.
℅ David Anderson
Principle Consultant
Tech2Med, LLC
6450 Old Darby TRL NE
Ada, Michigan 49301

Re: K211783
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: June 4, 2021
Received: June 9, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, MPH
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211783

Device Name
TriMed Threaded Intramedullary Nail System

Indications for Use *(Describe)*

The TriMed Threaded IM Nail System is intended 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

(a)(1). Submitted By:

TriMed, Inc.
27533 Avenue Hopkins
Santa Clarita, CA 91355
United States of America

Contact Person: David Anderson
Principle Regulatory Consultant
Office – (574) 377-0111
Fax – (661) 254-8485

Date: August 6, 2021

(a)(2). Proprietary Name: TriMed Threaded Intramedullary Nail System

Common Name(s): Screw, Fixation, Bone

Classification Name: 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener

Regulatory Class: II
Product Codes: HWC

(a)(3). Predicate Device:

Primary Predicate
K192745 – Depuy Synthes Trauma Screws, Synthes (USA) Products LLC / DePuy Orthopaedics Inc. (Primary)

Other Predicate Device(s)
K170021 – SMV Scientific Cannulated Compression Screws, SMV Scientific
K202589 – APTUS Cannulated Compression Screws, Medartis AG

(a)(4). Device Description

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 Threaded IM Nails are offered in diameters ranging from 1.8mm – 3.0mm in diameter and lengths between 20mm and 70mm.

(a)(5). Indications for Use

The TriMed Threaded IM Nail System is intended 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

(a)(6). Technological Characterizes

The subject devices included in The TriMed Threaded IM Nail System are similar to predicate devices in material, size, and have the same indications for use.

(b)(1). Substantial Equivalence: - Non-Clinical Evidence Performance Data

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

(b)(2). Substantial Equivalence: - Clinical Evidence

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

(b)(3). Substantial Equivalence – Conclusions

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.