January 5, 2020

TirMed, Inc.
David Anderson
Principle Consultant
Tech2Med, LLC
6450 Old Darby TRL NE
Ada, MI 49301

Re: K192696
Trade/Device Name: TriMed ASET Foot Plating system
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 10, 2019
Received: October 11, 2019

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192696

Device Name
The TriMed ASET Foot System

Indications for Use *(Describe)*

The TriMed ASET™ Foot Plating System is intended for use in stabilization of fractures, revision procedures, joint fusion, reconstruction, deformity corrections, osteotomies, and non-unions of small bones of the feet.

Specific examples include:
First metatarsal osteotomies for hallux valgus and hallux varus correction including:
- Opening/closing base wedge osteotomies,
- Distal and proximal chevron osteotomies,

Arthrodesis of the first metatarsal cuneiform joint (Lapidus Fusion);
Arthrodesis of the first metatarsophalangeal joint (MTP) including:
- Primary MTP fusion due to hallux rigidus and/or hallux valgus,
- Revision MTP fusion,
- Revision of failed first MTP arthroplasty implant,

Metatarsal and Phalanges:
- Metatarsal and phalanges fractures and osteotomies;

Mid / Hindfoot Fusions:
- Tarsometatarsal (TMT) fusions/stabilization,
- Intercuneiform fusions.

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:	January 2, 2020
(a)(2). Proprietary Name:	TriMed ASET™ Foot Plating System
Common Name(s):	Plate, Fixation, Bone
Classification Name:	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class:	II
Product Codes:	HRS, HWC
(a)(3). Predicate Device:	K072740: Mondeal Extremity Bone Fixation System, Mondeal North America, Inc. (Primary) K152974: The ORTHOLOC® 3Di Foot Reconstruction System, Wright Medical Technology, Inc.

(a)(4). Device Description

The TriMed ASET™ Foot Plating System is a multi-indication total foot plating system which provides surgical options for fractures, osteotomes and arthrodesis of the forefoot, midfoot and hindfoot. Plates and screws are made from implant grade titanium and titanium alloy. Implant offerings are as followed: 1St MTP fusion plates, Lapidus (With and without hooks) plates, Universal Straight plates, Universal Hook plates, and Universal T-Plates. 2.7mm, 3.5mm, and 4.0mm variable angle and non-locking screws are also included.

(a)(5). Indications for Use

The TriMed ASET™ Foot Plating System is intended for use in stabilization of fractures, revision procedures, joint fusion, reconstruction, deformity corrections, osteotomies, and non-unions of small bones of the feet.

Specific examples include:

First metatarsal osteotomies for hallux valgus and hallux varus correction including:

- Opening/closing base wedge osteotomies,
- Distal and proximal chevron osteotomies,

Arthrodesis of the first metatarsal cuneiform joint (Lapidus Fusion);

Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Primary MTP fusion due to hallux rigidus and/or hallux valgus,
- Revision MTP fusion,
- Revision of failed first MTP arthroplasty implant,

Metatarsal and Phalanges:

- Metatarsal and phalanges fractures and osteotomies;

Mid / Hindfoot Fusions:

- Tarsometatarsal (TMT) fusions/stabilization,
- Intercuneiform fusions.

(a)(6). Technological Characterizes

The subject devices included in The TriMed ASET™ Foot Plating System are similar to predicate devices in material, size, and bending strength. The subject plates differ slightly in geometry and may contain hook features.

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

The plates were evaluated against the predicate in static and fatigue three-point bend testing. The subject plates were stronger in static bending and equivalent in fatigue bending. The screws were evaluated in ASTM F543 torsional strength testing, insertion/removal torque testing and axial pullout testing. The subject screws were stronger in torsion testing and pullout testing. The insertion torque was equivalent to the predicate and was appropriate compared to the torsional strength.

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

N/A

(b)(3). Substantial Equivalence – Conclusions

TriMed ASET™ Foot Plating System plate, screw, 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 TriMed ASET™ Foot Plating System with the predicate devices.