April 17, 2024

TriMed, INC
Anderson David
Regulatory Affairs Contractor
27533 Avenue Hopkins
Valencia, California 91355

Re: K233863
Trade/Device Name: TriMed ASET Foot Plating System (1ST MTP 9-hole Long Plate), TriMed ASET Foot Plating System (1st Met Osteotomy Plate), TriMed ASET Foot Plating System (H-Plate), TriMed ASET Foot Plating System (Talonavicular Plate), TriMed ASET Foot Plating System (Calcaneal Slide Osteotomy Plate), TriMed ASET Foot Plating System (Evans Osteotomy Plate), TriMed ASET Foot Plating System (Medial Column Fusion Plate), TriMed ASET Foot Plating System (Straight Plate), TriMed ASET Foot Plating System (T-Plate)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: December 5, 2023
Received: December 6, 2023

Dear Anderson David:

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)*

K233863

Device Name

TriMed ASET Foot Plating System (1ST MTP 9-hole Long Plate);
TriMed ASET Foot Plating System (1st Met Osteotomy Plate);
TriMed ASET Foot Plating System (H-Plate);
TriMed ASET Foot Plating System (Talonavicular Plate);
TriMed ASET Foot Plating System (Calcaneal Slide Osteotomy Plate);
TriMed ASET Foot Plating System (Evans Osteotomy Plate);
TriMed ASET Foot Plating System (Medial Column Fusion Plate);
TriMed ASET Foot Plating System (Straight Plate);
TriMed ASET Foot Plating System (T-Plate)

Indications for Use *(Describe)*

The TriMed ASET™ Foot Plating System is indicated for use in stabilization of fractures, revision procedures, joint fusions, reconstructions, 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, Ludloff Osteotomy,

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 Fractures:
Cuneiform Fracture, Cuboid Fracture, Navicular Fracture

Mid / Hindfoot Fusions:
Tarsometatarsal (TMT) Fusions/Stabilization, Intercuneiform Fusions, Navicular Cuneiform (NC) Fusion, Talonavicular (TN) Fusion, Calcaneocuboid (CC) Fusion, Medial Column Fusion, Medial Column Fusion (talus, navicular, cuneiform, metatarsal) for neuropathic osteoarthropathy (Charcot), Lateral Column Fusion (calcaneus, cuboid, metatarsal) for neuropathic osteoarthropathy (Charcot)

Mid / Hindfoot Osteotomies (Deformity Corrections):
Lateral Column Lengthening (Evans Osteotomy), Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy), Medial Displacement Calcaneal Osteotomy

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

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	(574) 377-0111
Applicant Contact	David Anderson
Applicant Contact Email	david.anderson@tech2medllc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TriMed ASET Foot Plating System (1ST MTP 9-hole Long Plate); TriMed ASET Foot Plating System (1st Met Osteotomy Plate); TriMed ASET Foot Plating System (H-Plate); TriMed ASET Foot Plating System (Talonavicular Plate); TriMed ASET Foot Plating System (Calcaneal Slide Osteotomy Plate); TriMed ASET Foot Plating System (Evans Osteotomy Plate); TriMed ASET Foot Plating System (Medial Column Fusion Plate); TriMed ASET Foot Plating System (Straight Plate); TriMed ASET Foot Plating System (T-Plate)
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code	HRS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192696	TriMed ASET Foot Plating System	HRS
K222194	Baby Gorilla/Gorilla Plating System	HRS
K072740	Mondeal Extremity Bone Fixation System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

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, 1st MTP Osteotomy plates, H-Plate, Talonavicular Plate, Calcaneal Slide Osteotomy Plate, Evans Osteotomy Plate, Medial Column Fusion Plate, 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The TriMed ASET™ Foot Plating System is indicated for use in stabilization of fractures, revision procedures, joint fusions, reconstructions, 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, Ludloff Osteotomy,

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 Fractures:
Cuneiform Fracture, Cuboid Fracture, Navicular Fracture

Mid / Hindfoot Fusions:
Tarsometatarsal (TMT) Fusions/Stabilization, Intercuneiform Fusions, Navicular Cuneiform (NC) Fusion, Talonavicular (TN) Fusion, Calcaneocuboid (CC) Fusion, Medial Column Fusion, Medial Column Fusion (talus, navicular, cuneiform, metatarsal) for neuropathic osteoarthropathy (Charcot), Lateral Column Fusion (calcaneus, cuboid, metatarsal) for neuropathic osteoarthropathy (Charcot)

Mid / Hindfoot Osteotomies (Deformity Corrections):
Lateral Column Lengthening (Evans Osteotomy), Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy), Medial Displacement Calcaneal Osteotomy

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

The TriMed ASET Foot Plating system has the same Indications for Use as the referenced predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

TriMed ASET Foot Plating System devices are substantially equivalent to the predicate devices in which basic design features, manufacturing, packaging, and labeling are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness.

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

The TriMed ASET Foot Plating System implants were tested per the recommendations cited in the FDA Guidance Document, Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff. Static and dynamic four-point bending were conducted per ASTM F382-17.

The TriMed ASET Calcaneal Sliding Osteotomy Plate was tested for static bending. Testing showed that loading was greater or equal to the referenced predicate device.

Clinical studies were not conducted for the subject devices.

Based on the indications for use, technological characteristics, and the summary of data submitted, TriMed Inc. has determined that the proposed devices are substantially equivalent to the currently marketed predicate device.