September 1, 2023

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

Re: K230805
Trade/Device Name: TriMed Clavicle Fixation 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: June 5, 2023
Received: June 5, 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 (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 -S

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)*

K230805

Device Name
TriMed Clavicle Fixation System

Indications for Use *(Describe)*

The TriMed Clavicle Fixation Plates and Screws are indicated for use in fixation of fractures, malunions, non-unions, and osteotomies of the clavicle.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K230805
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 31, 2023

(a)(2). Proprietary Name: TriMed Clavicle Fixation System

Common Name(s):
Plate, Fixation, Bone
Screw, Fixation, Bone

Classification Name:
21 CFR 888.3030 (Primary): Single/multiple component metallic bone fixation appliances and accessories.
21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener

Regulatory Class: II
Product Codes: HRS (Primary), HWC

(a)(3). Predicate Device:
Primary Predicate Device
K112509 – TriMed Clavicle Fixation System, TriMed, Inc. (USA)
Additional Predicate Device
K201321 – DePuy Synthes 2.7mm VA LCP Clavicle Plate System (CHE)

(a)(4). Device Description

The TriMed Clavicle Fixation System is a multi-indication plate and screw fixation system which provides surgical options for fractures, malunions, non-unions and osteotomies of the Clavicle.

TriMed Clavicle Plates have been updated for better plate contour fit to bone, updated lengths (so there is less subcutaneous plate prominence for the patient), and reduced plate thickness. TriMed Clavicle Plates are compatible with 2.7mm / 3.2mm locking and non-locking screws.

All TriMed plates and screws are manufactured from implant grade 316 stainless steel.

(a)(5). Indications for Use

The TriMed Clavicle Fixation Plates and Screws are intended for use in fixation of fractures, malunions, non-unions, and osteotomies of the clavicle.

(a)(6). Technological Characteristics

The subject TriMed Clavicle Fixation System devices are similar to the predicate devices in material, size, packaging, sterility, and has similar indications for use. The TriMed Subject devices have been updated for better plate contour fit to bone, updated lengths (so there is less subcutaneous plate prominence for the patient), and reduced plate thickness as compared to predicate devices (K112509). Plate thickness and length ranges are comparable to predicate devices (K201321).

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

TriMed Clavicle Fixation System Implants were evaluated for following:

- Static and endurance 4-point bending per ASTM F382-17.
- Cytotoxicity, Sensitization and Irritation testing in accordance with ISO 10993-1:2018
- All system screws were tested per FDA Guidance FDA-2019-D-1652 (ASTM D543-17) for:
    - 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 Clavicle Fixation System devices are substantially equivalent to the predicate devices in which basic design features, intended uses, indications for use, 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.

Mechanical testing data and engineering analyses show the subject devices are substantially equivalent to that of the predicate devices for the desired indications.

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.