June 1, 2022

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

Re: K220650
Trade/Device Name: TriMed Ripcord Device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: March 4, 2022
Received: March 7, 2022

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,

Laura C. Rose, Ph.D.
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)*
K220650

Device Name
TriMed RipCord Device

Indications for Use *(Describe)*

TriMed Ripcord devices are intended for use to supplement repair or reconstruction during healing of ligament injuries or deficiencies of the extremities.

The TriMed RipCord device is indicated to be used as an adjunct in combination with compatible TriMed fixation implants to provide fixation during the healing process in syndesmotic trauma, such as fixation of syndesmosis disruptions in connection with Weber B and C ankle fractures.

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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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: May 19, 2021

(a)(2). Proprietary Name: TriMed RipCord Device

Common Name(s): Button / Suture

Classification Name: 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories.

Regulatory Class: II
Product Codes: HTN

(a)(3). Predicate Device:

Primary Predicate
K130033 – ToggleLoc System (ToggleLoc with Ziptight), Biomet (USA) (Primary)

Other Predicate Device(s)
K201522 – Arthrex Syndesmosis TightRope XP Buttress Plate Implant System, Arthrex Inc. (USA)

(a)(4). Device Description

The TriMed RipCord Suture Button implant (RipCord Device) is a non-bioabsorbable suture/button implantable device used as an aid for the treatment of ligament injuries, deficiencies, or reconstruction. The TriMed RipCord Suture Button Implant comprises of, a far side 316L stainless-steel Button, near side 316L stainless-steel button, and ultra-high molecular weight polyethene (UHMWPE) braided suture. The implantable device is packaged with various ancillary instruments to aid in insertion. The implantable devices and various ancillary instruments are provided sterile and are single use.

(a)(5). Indications for Use

TriMed RipCord devices are intended for use to supplement repair or reconstruction during healing of ligament injuries or deficiencies of the extremities.

The TriMed RipCord device is indicated to be used as an adjunct in combination with compatible TriMed fixation implants to provide fixation during the healing process in syndesmotic trauma, such as fixation of syndesmosis disruptions in connection with Weber B and C ankle fractures.

(a)(6). Technological Characterizes

The subject TriMed RipCord Device is similar to the predicate devices in material, size, packaging, sterility, and has similar indications for use.

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

The TriMed RipCord Device implants were tested for the following:

- Cyclic endurance
- Static load displacement
- Pull through needle testing
- Cyclical shear endurance
- Bacterial Endotoxins Test (BET) per ANSI/AAMI ST72: 2019 and USP <85>
- Cytotoxicity, Sensitization and Irritation testing in accordance with ISO 10993-1:2018

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

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

(b)(3). Substantial Equivalence – Conclusions

The TriMed RipCord Device is substantially equivalent to the predicate device in which the basic design features and intended uses 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.

The submitted mechanical testing data demonstrates that the cyclic fatigue, maximum static loading, needle pull through, and cyclical shear of the subject device is substantially equivalent to that of the predicate device 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 device is substantially equivalent to the currently marketed predicate device.