July 11, 2025

TriMed, Inc.
Divya Raghavi Nandakumar
Regulatory Affairs Supervisor
27533 Avenue Hopkins
Santa Clarita, California 91355

Re: K251134
Trade/Device Name: RipCord
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN, HWC
Dated: April 10, 2025
Received: April 11, 2025

Dear Divya Raghavi Nandakumar:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251134

Please provide the device trade name(s).

RipCord

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251134

510(k) Summary

Prepared on: 2025-07-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	TriMed, Inc.
Applicant Address	27533 Avenue Hopkins Santa Clarita CA 91355 United States
Applicant Contact Telephone	6612557406
Applicant Contact	Mrs. Divya Raghavi Nandakumar
Applicant Contact Email	ra@trimedortho.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	RipCord
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Washer, Bolt Nut
Regulation Number	888.3030
Product Code(s)	HTN, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220650	TriMed RipCord Device	HTN
K130033	ToggleLoc System (ToggleLoc with Ziptight)	MBI

Device Description Summary

21 CFR 807.92(a)(4)

The TriMed RipCord Screw is a single-use, sterile, non-absorbable implantable device designed to aid in the treatment of syndesmotic injuries of the lower extremities. The device consists of a far button, an ultra-high molecular weight polyethylene (UHMWPE) suture, and a cannulated screw.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both RipCord Screw and the primary predicate device cleared under K220650 are indicated for use to supplement repair or reconstruction during healing of ligament injuries or deficiencies of the extremities. The indications for use statements are the same.

The subject device is also substantially equivalent in indications for use to the secondary predicate/reference device cleared under

K130033 (Zimmer Biomet ZipTight Fixation System). Both are indicated for syndesmosis fixation due to syndesmotic disruptions.

Technological Comparison

21 CFR 807.92(a)(6)

TriMed RipCord Screw is substantially equivalent to primary predicate cleared under K220650 in terms of material, design features, principles of operation, manufacturing, packaging, and labeling. Any differences in technological characteristics do not raise new questions of safety or effectiveness and are consistent with established design principles for syndesmotic fixation systems.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

TriMed RipCord Screw devices were subjected to static loading and cyclic endurance testing. TriMed RipCord Screw devices successfully met the established acceptance criteria, demonstrating performance equivalence to the predicate device cleared under K220650.

TriMed Cannulated Hex 3.2mm screws were subjected to torsional strength, driving torque and axial pullout tests 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. Test samples met the acceptance criteria.

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 TriMed RipCord Screw is substantially equivalent to the predicate device (TriMed RipCord) cleared under K220650.