July 1, 2019

TriMed, Inc.
℅ Jean Asquith
Regulatory Affairs Consultant
Jean Asquith
4221 Lost Oasis Hollow
Austin, Texas 78739

Re: K190166
Trade/Device Name: TriMed Nitinol Staple System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: May 24, 2019
Received: May 30, 2019

Dear Jean Asquith:

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,

For Vesa Vuniqi
Acting Assistant Director
DHT6A: Division of Joint Arthroplasty 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)*
K190166

Device Name
TriMed Nitinol Staple System

Indications for Use *(Describe)*

The TriMed Nitinol Staple System is intended for use in fractures, osteotomy, and arthrodesis of the following areas of the body: small bones in the hand and foot.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

1. SUBMITTER INFORMATION

TriMed, Inc.
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Santa Clarita, CA 91355

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510(k) Consultant Contact:	Jean Asquith
	Tel: (512) 680-5802
Email:	jtasquith.ra@gmail.com

Date Prepared:	June 21, 2019

2. DEVICE IDENTIFICATION

Device Trade Name:	TriMed Nitinol Staple
Device Common Name:	Staple, Fixation, Bone
Regulation Number:	21 CFR 888.3030
Regulation Description:	Single/multiple component metallic bone fixation appliance and accessories
Product Code:	JDR
Device Class:	Class II
Classification Panel:	Orthopedic

3. DEVICE DESCRIPTION

The TriMed Staple is a sterile, non-bioabsorbable, implantable device designed to address common types of deformity corrections, fusions, fractures and osteotomies in extremities amenable to staple fixation, all depending on the size, shape, and location of the fractured bone and bone fracture fragments. TriMed Staples are manufactured from medical grade Nitinol. Two types of staple leg configuration are available; symmetrical and asymmetrical. The staple is implanted with a set of re-usable instruments designed for: preparation of the implant site and insertion of the implant into bone.

4. INDICATIONS FOR USE

The TriMed Nitinol Staple System is intended for use in fractures, osteotomy, and arthrodesis of the following areas of the body: small bones in the hand and foot.

5. COMPARISON TO PREDICATE DEVICES

The TriMed Nitinol Staple System is substantially equivalent to the following device:

510(k) Number	Device	Applicant
K112794	Eleos Staple (included as part of the TriMed EOS Small Bone Fixation System)	TriMed

The TriMed Nitinol Staple is substantially equivalent to the Eleos Staple when comparing the following characteristics:

- Intended Use
- Principles of Use
- Fundamental Technology
- Basic Design
- Materials Used
- Where used
- Sterilization Method

6. TESTING AND PERFORMANCE DATA

To demonstrate product performance, TriMed conducted the following tests and compared the results to the predicate device.

- Pull-Out Fixation Strength;
- Elastic Static Bending;
- Constant Amplitude Bending Fatigue;
- Corrosion Susceptibility Testing; and
- Quantification of the titanium oxide layer thickness

In addition, the transformation temperature (A_f) was quantified.

7. CONCLUSIONS

The TriMed Nitinol Staple is substantially equivalent to the predicate device as the basic design features and intended uses are the same. Any differences between the subject and predicate devices are considered minor and do not raise questions concerning safety or effectiveness. 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.