November 21, 2022

Treace Medical Concepts
Brittany Grochala
Sr. Regulatory Affairs Specialist
203 Fort Wade Road, Suite 150
Ponte Vedra, Florida 32081

Re: K222645
Trade/Device Name: Treace Medical Concepts (TMC) Implant 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: JDR
Dated: August 31, 2022
Received: September 1, 2022

Dear Brittany Grochala:

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,

Limin Sun -S

Limin Sun, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222645

Device Name
Treace Medical Concepts (TMC) Compression Implant System

Indications for Use *(Describe)*
The system is intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Treace Medical Concepts (TMC) Compression Implant System
August 31st, 2022

Company:	Treace Medical Concepts, Inc. 203 Fort Wade Road, Suite 150 Ponte Vedra, FL 32081
Establishment Registration:	3011623994
Primary Contact:	Brittany Grochala, Sr. Regulatory Affairs Specialist Phone: 515-865-0494 Fax: 904-834-7169 Email: bgrochala@treace.net
Secondary Contact:	Kristina Hall, Director, Regulatory Affairs Phone: 904-373-5940 ext. 1321 Fax: 904-834-7169 Email: khall@treace.net
Trade Name:	Treace Medical Concepts (TMC) Compression Implant System
Common Name:	Staple, Fixation, Bone
Classification:	Class II
Regulation Number:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories.
Panel:	87- Orthopedic
Product Code(s):	JDR Staple, Fixation, Bone

Predicate Device(s):
Primary Predicate:
- Z-Medical Z-Staple (K121277, S.E. 11/07/2012)

Additional Predicate:
- Wright Medical FuseForce™ Flex Dynamic Compression System (K203832, S.E. 05/07/2021)

Reference Device:
- Treace Medical Concepts (TMC) Plating System (K220136, S.E. 02/16/2022)

Device Description:
The Treace Medical Concepts (TMC) Compression Implant System consists of implants and related instrumentation for implantation. The implant is offered in multiple combinations of bridge lengths, leg lengths, cross sections and cannulated versions to accommodate various anatomies. The system is intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle.

The purpose of this traditional 510(k) submission is for the introduction of the Treace Medical Concepts (TMC) Compression Implant System.

All implantable components are manufactured from implant grade titanium alloy (Ti-6Al-4V-ELI) per ASTM F136 and are provided sterile by gamma irradiation.

Indications for Use:
The system is intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle.

Substantial Equivalence:
The subject TMC Compression Implant System is substantially equivalent to the following predicate and reference devices:

Primary Predicate:
- Z-Medical Z-Staple (K121277, S.E. 11/07/2012)

Additional Predicate:
- Wright Medical FuseForce™ Flex Dynamic Compression System (K203832, S.E. 05/07/2021)

Reference Device:
- Treace Medical Concepts (TMC) Plating System (K220136, S.E. 02/16/2022)

The subject compression implants are intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle, equivalent to the predicate devices. The subject compression implants are manufactured from implant grade titanium alloy (Ti-6Al-4V-ELI) per ASTM F136 and also share similar materials, geometry, construction, packaging, and overall design with the predicate and reference devices (Z-Staple and TMC Plating System). Thus, it can be concluded that the subject devices do not raise new questions about safety and effectiveness and are substantially equivalent to the predicate and reference devices.

Performance Testing:
The subject device was compared to the primary predicate device, Z-Medical Z-Staples, per ASTM F564 for Bone Metallic Staples. The testing demonstrated that the subject device met all acceptance criteria. Therefore, the subject device is substantially equivalent to the predicate device.

Conclusion:
The TMC Compression Implant System has similar intended use, overall design, materials, and mechanical properties to that of the predicate and reference devices. Therefore, it can be concluded that the subject device is at least as safe and effective and substantially equivalent to the predicate and reference devices.