August 28, 2023

Treace Medical Concepts
Brittany Grochala
Sr. Regulatory Affairs Specialist
100 Palmetto Park Place
Ponte Vedra, Florida 32081

Re: K232387
Trade/Device Name: Treace Medical Concepts (TMC) Compression Implant 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 8, 2023
Received: August 9, 2023

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)*

K232387

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.

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510(k) Summary
Treace Medical Concepts (TMC) Compression Implant System
August 08, 2023

Company:	Treace Medical Concepts, Inc. 100 Palmetto Park Place 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):	Primary: JDR

Predicate Device(s):
Primary Predicate:
- TMC Compression Implant System (K222645, S.E. 11/21/2022)

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

Device Description:
The TMC Compression Implant System consists of implants and related instrumentation for implantation. The implants are offered in multiple combinations of bridge lengths, leg lengths, and cross sections to accommodate various anatomies. This includes two (2x1) or four (2x2, 4x1) legged implants. The system is intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle.

The purpose of this Special 510(k) submission is to expand the implant and instrument options for the TMC Compression Implant System. The subject implants and instruments are modifications of the previously cleared TMC Compression Implant System (K222645).

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 devices:

Primary Predicate:
- TMC Compression Implant System (K222645, S.E. 11/21/2022)

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

The subject compression implants are intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle, identical or equivalent to the predicate devices. The subject compression implants are manufactured from implant grade titanium alloy (Ti-6Al-4V-ELI) per ASTM F136, identical to the predicate devices.

The subject device modifications include updates to the implant bridge geometry, leg diameter, leg length, leg profile, and an anatomic leg location design (4x1 implant only). The subject 2x1 and 4x1 compression implants include thinner bridges and the subject 4x1 implants have shorter legs as compared to the primary predicate. The subject 2x1 implants have larger leg diameters while the leg lengths remain unchanged as compared to the primary predicate.

The subject implants were compared to the additional predicate per ASTM F564-17 Standard Specification and Test Methods for Metallic Bone Staples. Mechanical testing including bending and pull-out performance have been completed to evaluate the subject device against the additional predicate device. These are the same well-established methods utilized in the original, primary predicate TMC Compression Implant System submission (K222645). The testing demonstrated that the subject device met all acceptance criteria.

The subject devices share similar materials, geometry, construction, packaging, overall design, and performance with the predicate devices. 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 devices.

Performance Testing:
The subject devices were compared to the predicate device, Z-Medical Z-Staples, in bending performance and pullout performance testing per ASTM F564 Standard Specification and Test Methods 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 subject TMC Compression Implant System has similar intended use, overall design, materials, and mechanical properties to that of the predicate devices. Moreover, there is no change in the intended use as compared to the predicate TMC Compression Implant System. Therefore, it can be concluded that the subject device is at least as safe and effective and substantially equivalent to the predicate devices.