December 26, 2024

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

Re: K243658
Trade/Device Name: 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, HWC
Dated: November 26, 2024
Received: November 27, 2024

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 (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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243658

Device Name

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.

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510(k) Summary
TMC Compression Implant System November 26, 2024

Company:	Treace Medical Concepts, Inc. 100 Palmetto Park Place Ponte Vedra, FL 32081
Establishment Registration:	3011623994
Primary Contact:	Brittany Grochala, Senior Regulatory Affairs Specialist II Phone: 515-865-0494 Fax: 904-834-7169 Email: bgrochala@treace.net
Secondary Contact:	Kristina Hall, Sr. Director, Regulatory Affairs Phone: 904-373-5940 ext. 1321 Fax: 904-834-7169 Email: khall@treace.net
Trade Name:	TMC Compression Implant System
Common Name:	Primary: Staple, fixation, bone Subsequent: Screw, fixation, bone
Classification:	Class II
Regulation Number:	21 CFR 888.3030 21 CFR 888.3040
Panel:	87- Orthopedic
Product Code(s):	Primary: JDR Subsequent: HWC

Predicate Device(s):

- Primary Predicate: TMC Compression Implant System (K242415, S.E. 09/06/2024)
- Additional Predicate: Stryker EasyClip Memory Metal Staples (K122113, S.E. 03/12/2013)
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Device Description:

TMC Compression Implant System is comprised of staple implants and related instrumentation for implantation. The implants are offered in multiple combinations of bridge lengths, leg lengths, cross sections, and cannulated versions to accommodate various anatomies. This includes two (2x1) or four (2x2, 4x1) legged implants. It also includes locking screws for additional fixation. All implantable components are manufactured from implant grade titanium alloy (Ti-6Al-4V-ELI) per ASTM F136 and are provided sterile by gamma irradiation.

The changes described within this submission do not impact reprocessing, sterility, shelf-life, and biocompatibility considerations in comparison to the predicate device. The software, cybersecurity, EMC, and wireless technology sections are not applicable to the subject device.

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 (K242415, S.E. 09/06/2024)
- Additional Predicate: Stryker EasyClip Memory Metal Staples (K122113, S.E. 03/12/2013)

The subject compression implants are intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle, identical or similar to the predicate devices. Additionally, the subject compression implants are manufactured using wrought titanium alloy Ti-6Al-4V-ELI per ASTM F136 and Type II anodized identical to the primary TMC Compression Implant System predicate devices.

The subject device modifications include the introduction of additional two (2) tine staples and associated instrumentation for implantation to the TMC Compression Implant System. The modifications include updates to the bridge geometry, tine diameter, and tine length. The 4x1 staple design remains unchanged.

The subject devices share the same or 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:

Mechanical testing and analysis per ASTM F564-17 Standard Specification and Test Methods for Metallic Bone Staples was completed to evaluate the fatigue strength of the subject staples using a four-point bending test (Annex A1) and pull-out strength (Annex A2) in comparison to the predicate devices. The testing and analysis demonstrated that the subject devices met all acceptance criteria and therefore are substantially equivalent to the predicate devices.

Conclusion:

The subject TMC Compression Implant System has a 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 primary 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.