February 16, 2022

Treace Medical Concepts, Inc.
% Dawn Norman
Partner
MRC Global, LLC
9085 E Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K220136
Trade/Device Name: Treace Medical Concepts (TMC) Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 14, 2022
Received: January 18, 2022

Dear Dawn Norman:

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: Shumaya Ali, M.P.H.
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

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)*
K220136

Device Name
Treace Medical Concepts (TMC) Plating System

Indications for Use *(Describe)*
The TMC Plating System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet. The system can be used in both adult and pediatric patients aged >12 years. In the foot, the system can be used for the following specific examples:

- First metatarsal osteotomies for hallux valgus correction such as:
• Opening base wedge osteotomy
• Closing base wedge osteotomy
• Crescentic osteotomy
• Proximal Chevron osteotomy
• Distal Chevron osteotomy (Austin)
- First metatarsal fracture fixation
- Arthrodesis of the tarsometatarsal (TMT) joints or the 1st metatarsophalangeal (MTP) joint for the treatment of deformity (e.g., hallux valgus, hallux rigidus, metatarsus adductus) and / or arthritis
- Flatfoot Osteotomies
• Lateral Column Lengthening (Evans Osteotomy)
• Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Mid / Flatfoot Fusions
• LisFranc Arthrodesis and/or Stabilization
• lntercuneiform Fusions
• Navicular-Cuneiform (NC) Fusion
• Talo-Navicular (TN) Fusion
• Calcaneo-Cubiod (CC) Fusion
- Medial Column Fusion

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

Treace Medical Concepts (TMC) Plating System

February 15, 2022

Company: Treace Medical Concepts, Inc.
203 Fort Wade Rd., Suite 150
Ponte Vedra, FL 32081

Primary Contact: Dawn Norman
Partner, MRC Global
Phone: 618-604-3064
Dawn.Norman@askmrcglobal.com

Company Contact: Kristina Hall
Regulatory Affairs Director
Treace Medical Concepts, Inc.
Phone: 904.373.5940
khall@treace.net

Trade Name:	**Treace Medical Concepts (TMC) Plating System**
Common Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Classification:	Class II
Regulation Number:	21 CFR 888.3030 (Single/multiple component metallic bone fixation appliances and accessories) (primary) 21 CFR 888.3040 (Smooth or threaded metallic bone fixation fastener)
Panel:	87- Orthopedic
Product Code:	HRS; HWC
Primary Predicate:	K200961 TMC Plating System

Device Description:

The Treace Medical Concepts (TMC) Plating System includes straight, L-shaped, H- shaped, curved and Python plates and associated screws. The plates and screws are intended for use in stabilization and fixation of fractures, revision procedures, fusions, and reconstructions (osteotomy) of small bones of the foot.

The purpose of this special 510(k) is to clarify the indications for use for the Treace Medical Concepts (TMC) Plating System (K192504 and K200961).

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

Indications for Use:
The TMC Plating System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet. The system can be used in both adult and pediatric patients aged >12 years. In the foot, the system can be used for the following specific examples:

- First metatarsal osteotomies for hallux valgus correction such as:
    - Opening base wedge osteotomy
    - Closing base wedge osteotomy
    - Crescentic osteotomy
    - Proximal Chevron osteotomy
    - Distal Chevron osteotomy (Austin)

- Arthrodesis of the tarsometatarsal (TMT) joints or the 1st metatarsophalangeal (MTP) joint for the treatment of deformity (e.g., hallux valgus, hallux rigidus, metatarsus adductus) and / or arthritis

- First metatarsal fracture fixation
- Flatfoot Osteotomies
    - Lateral Column Lengthening (Evans Osteotomy)
    - Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Mid / Flatfoot Fusions
    - LisFranc Arthrodesis and/or Stabilization
    - lntercuneiform Fusions
    - Navicular-Cuneiform (NC) Fusion
    - Talo-Navicular (TN) Fusion
    - Calcaneo-Cubiod (CC) Fusion
- Medial Column Fusion

Substantial Equivalence:
The subject TMC Plating System is substantially equivalent to the predicate TMC Plating System previously cleared in K143717, K153531, K183321, K192504, and K200961.

The subject TMC Plating System is manufactured from titanium (Ti-6Al-4V-ELI) and is intended to be used in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet, identical to the predicate devices. Indications for use have been clarified and were found through a risk analysis including literature review to be equivalent to the predicate device. The subject TMC Plating System also shares similar geometry, and construction with the predicate devices.

Thus, it can be concluded that the subject changes to the Indications for Use do not raise new questions about safety and effectiveness.

Performance Testing:
Performance testing was not required to support the clarification of the indications statement.

Conclusion:
The Treace Medical Concepts (TMC) Screw Fixation System has identical design and construction to the predicate devices. A risk analysis found that the Indications for Use statement remain substantially equivalent to those of the system in previous clearances. Therefore, it can be concluded that the subject device is as safe, as effective, and performs as safely and effectively as the predicate device.