February 22, 2024

Treace Medical Concepts Inc.
Melissa Coloroso
Principal Regulatory Affairs Specialist
100 Palmetto Park Place
Ponte Vedra, Florida 32081

Re: K240173
Trade/Device Name: Treace Medical Systems (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 22, 2024
Received: January 23, 2024

Dear Melissa Coloroso:

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.

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,

Shumaya Ali -S

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)*
K240173

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 the feet. The system can be used in both pediatric (aged >12-21) and adult (aged 22 and over) patients. In the foot, the system can be used for the following specific examples:

* Osteotomy of the 1st metatarsal for the treatment of deformity (e.g., hallux valgus) such as:
- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic osteotomy
- Proximal Chevron osteotomy
- Distal Chevron osteotomy (Austin)
- Transverse osteotomy
* 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
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (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 22, 2024

Company:	Treace Medical Concepts, Inc. 100 Palmetto Park Place Ponte Vedra, FL 32081
Establishment Registration:	3011623994
Primary Contact:	Melissa Coloroso, Principal Regulatory Affairs Specialist Phone: 303-641-8592 Fax: 904-834-7169 Email: mcoloroso@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:	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 appliance and accessories and accessories) (primary) 21 CFR 888.3040 (Smooth or threaded metallic bone fixation fastener)
Panel:	87- Orthopedic
Product Code(s):	HRS, HWC

Predicate Device(s):

- Primary Predicate:
  Treace Medical Concepts (TMC) Plating System (K221181, S.E. 01/05/2023)
- Additional Predicate(s):
  - Treace Medical Concepts (TMC) Screw Fixation System (K213036, S.E.10/21/2021)
  - CrossRoads Extremity Systems LLC., MIS Bunion System (K181872, S.E. 02/19/2019)
  - OrthoHelix Surgical Designs Inc., Mini MaxLock Extreme Plating System (K101962, S.E. 09/27/2010)

Device Description:
The Treace Medical Concepts (TMC) Plating System includes straight, L-shaped, H- shaped, anatomically curved plates, and intramedullary plates. The system includes 2.5mm, 2.7mm, and 3.0mm diameter cannulated and non-cannulated, locking, and non-locking screws ranging in lengths from 10-36mm. The plates and screws are intended for use in stabilization and fixation of

fractures, revision procedures, fusions, and reconstructions (osteotomy) of the foot.

All implantable components are manufactured from implant grade titanium alloy (Ti6Al4V-ELI) per ASTM F136 and are provided sterile by gamma irradiation.

The primary purpose of this special 510(k) submission is to introduce additional plate and screw options and accompanying instrumentation within the Treace Medical Concepts (TMC) Plating System. Secondly, Treace is providing the Agency notification regarding minor modifications implemented for the Treace Medical Concepts (TMC) Plating System via internal documentation.

The changes described within this submission do not impact reprocessing, sterility, 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 TMC Plating System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of the feet. The system can be used in both pediatric (aged >12-21) and adult (aged 22 and over) patients. In the foot, the system can be used for the following specific examples:

- Osteotomy of the 1st metatarsal for the treatment of deformity (e.g., hallux valgus) such as:
    - Opening base wedge osteotomy
    - Closing base wedge osteotomy
    - Crescentic osteotomy
    - Proximal Chevron osteotomy
    - Distal Chevron osteotomy (Austin)
    - Transverse osteotomy
- 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
    - Intercuneiform Fusions
    - Navicular-Cuneiform (NC) Fusion
    - Talo-Navicular (TN) Fusion
    - Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion

Substantial Equivalence:
The subject TMC Plating System is substantially equivalent to the following predicate device:

- Primary Predicate:

Treace Medical Concepts (TMC) Plating System (K221181, S.E. 01/05/2023)

- Additional Predicate(s):
  - Treace Medical Concepts (TMC) Screw Fixation System (K213036, S.E. 10/21/2021)
  - CrossRoads Extremity Systems LLC., MIS Bunion System (K181872, S.E. 02/19/2019)
  - OrthoHelix Surgical Designs Inc., Mini MaxLock Extreme Plating System (K101962, S.E. 09/27/2010)

The subject TMC Plating System is manufactured from implant grade titanium alloy (Ti6Al4V-ELI) per ASTM F136 and is intended to be used in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of the feet, identical to the primary predicate device.

The subject TMC Plating System shares similar materials, geometry, construction, and overall design with the predicate devices. The technological differences between the subject and predicate devices include geometric modifications and additional fixation options. Any differences in the technological characteristics of the predicate devices do not raise any new questions of safety and effectiveness. 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 analysis including static and dynamic 4-point bend testing and static torsion, driving torque, removal torque, and axial pullout engineering analysis based on ASTM F382 and ASTM F543 were performed between the subject and predicate plating systems. Further, engineering analysis of the worst-case cross-sections and geometries on the subject and predicate devices was performed. The mechanical testing, engineering analysis, cross-sectional, and geometrical analysis demonstrated that the subject devices did not present a new worst-case with regards to mechanical performance per ASTM F382 and ASTM F543 when compared to their predicate devices. The subject devices are substantially equivalent to the predicate devices.

Conclusion:
The Treace Medical Concepts (TMC) Plating System has similar intended use, overall design, materials, and mechanical properties to that of the predicate devices. Therefore, it can be concluded that the subject devices are at least as safe and effective and are substantially equivalent to the predicate devices.