October 30, 2019

Treace Medical Concepts, Inc.
% Dawn Norman
Executive Vice President
Memphis Regulatory Consulting, LLC
6075 Poplar Avenue, Suite 500
Memphis, Tennessee 38119

Re: K192504

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: September 28, 2019
Received: September 30, 2019

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
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.


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
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. 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 first metatarsal-cuneiform joint (Lapidus Fusion)
- 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
  • 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
  • Intercuneiform Fusions
  • Navicular-Cuneiform (NC) Fusion
  • Talo-Navicular (TN) Fusion
  • Calcaneo-Cubiod (CC) Fusion
- Medial Column Fusion
- Arthrodesis of the first metatarsalphalangeal joint (MTP)

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

Primary Contact: Dawn Norman  
Executive Vice President, MRC|X, LLC  
Phone: 618.604.3064  
dawn.norman@mrc-x.com  

Company/Secondary Contact: Rachel Osbeck  
VP, Quality Assurance & Regulatory Affairs  
Treace Medical Concepts, LLC  
Phone: 904.373.5940 Ext. 1304  
rosbeck@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)  
21 CFR 888.3040 (Smooth or threaded metallic bone fixation fastener)  

Panel: 87- Orthopedic  

Product Code: HRS and HWC  

Primary Predicate: K183321 Treace Medical Concepts (TMC) Plating System  

Device Description: The previously cleared Treace Medical Concepts (TMC) Plating System includes straight, L-shaped, and H-shaped, and Python plates and 2.5mm diameter screws in lengths ranging from
10-28mm. 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) submission is to expand the size ranges offered for the plates and screws, as well as add a curved plate option.

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. 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
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- First metatarsal fracture fixation
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- Flatfoot Osteotomies
  - Lateral Column Lengthening (Evans Osteotomy)
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- Mid / Flatfoot Fusions
  - LisFranc Arthrodesis and/or Stabilization
  - 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
  - Intercuneiform Fusions
  - Navicular-Cuneiform (NC) Fusion
  - Talo-Navicular (TN) Fusion
  - Calcaneo-Cubiod (CC) Fusion
- Medial Column Fusion
- Arthrodesis of the first metatarsophalangeal joint (MTP)

**Substantial Equivalence:**
The subject TMC Plating System is substantially equivalent to the predicate Treace Medical Concepts (TMC) Plating System (K183321, S.E. 01/25/2019; K153531, S.E. 01/07/2016; K143717, S.E. 03/19/2015).

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 not changed and are, thus, identical 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 does not raise new questions about safety and effectiveness.

**Performance Testing:**
Mechanical testing, including static and dynamic 4-point bend testing and static torsional and pullout testing have been performed per ASTM F382 and ASTM F543 on the subject plates and screws. The results have shown the larger plates and screws to be substantially equivalent to the previously cleared devices. Thus, the addition of these plates and screws does not present a new worst case.