May 8, 2020

Treace Medical Concepts, Inc.
℅ Danielle Besal
Principal Consultant
MRC Global
9085 East Mineral Circle, Suite
Centennial, Colorado 80112

Re: K200961
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: April 8, 2020
Received: April 10, 2020

Dear Danielle Besal:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200961

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 metatarsalcuneiform 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
  - lntercuneiform Fusions
  - Navicular-Cuneiform (NC) Fusion
  - Talo-Navicular (TN) Fusion
  - Calcaneo-Cubiod (CC) Fusion
- Medial Column Fusion
- Arthrodesis of the first metatarsophalangeal 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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510(k) Summary
Treace Medical Concepts (TMC) Plating System
May 7, 2020

Company:	Treace Medical Concepts, Inc. 203 Fort Wade Rd., Suite 150 Ponte Vedra, FL 32081
Primary Contact:	Danielle Besal Principal Consultant, MRC Global Phone: 901-827-8670 Danielle.Besal@askmrcglobal.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:	K192504 Treace Medical Concepts (TMC) Plating System

Device Description:
The previously cleared Treace Medical Concepts (TMC) Plating System includes straight, L-shaped, H- shaped, and Python plates and 2.5mm-3.0mm diameter screws in lengths ranging from 10-32mm. 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 add the Lapiplasty® Mini-Incision™ Plates to the TMC Plating System. The subject plates are based on the design of the previously cleared Lapiplasty® S1 Plate (K192504). The subject plates are used with the same screws as the predicate plate.

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
    - Closing base wedge osteotomy
    - Crescentic osteotomy
    - Proximal Chevron osteotomy
    - Distal Chevron osteotomy (Austin)
- First metatarsal fracture fixation
- Arthrodesis of the first metatarsalcuneiform 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
    - lntercuneiform 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 (K192504, S.E. 10/30/2019).

The subject plates are manufactured from titanium (Ti-6Al-4V-ELI) and are 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 identical to the predicate device. The subject plates also share similar geometry and construction with the predicate plate. Thus, it can be concluded that the subject does not raise different questions about safety and effectiveness.

Performance Testing:
Dynamic 4-point bend testing has been performed per ASTM F382 on the subject plates. The results have shown subject device to be substantially equivalent to the primary predicate. Additionally, an engineering analysis of the subject device concluded that its performance with respect to static 4-point bend testing is equivalent to the predicate device. Thus, the addition of these plates does not present a new worst case with respect to static or dynamic 4-point bend testing.

Conclusion:
The Treace Medical Concepts (TMC) Plating System has identical intended use, similarities in design and construction, and equivalent performance to the predicate device as demonstrated through bench testing and engineering analysis. Therefore, it can be concluded that the subject device is as safe, as effective, and performs at least as safely and effectively as the predicate device.