January 25, 2019

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

Re: K183321
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: November 28, 2018
Received: November 30, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K183321

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
January 25, 2019

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
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Company/Secondary Contact: Rachel Osbeck
Sr. Director, Quality Assurance
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

Device Description:
This traditional 510(k) is to obtain clearance for expanded indications for the Treace Medical Concepts (TMC) Plating System implants.

The subject TMC Plating System implants include a variety of previously cleared bone plates and screws. The plates and screws are intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet.

All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI) per ASTM F136.

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:

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- Flatfoot Osteotomies
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    - Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Mid / Flatfoot Fusions
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    - 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
    - lntercuneiform Fusions
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    - Talo-Navicular (TN) Fusion
    - Calcaneo-Cubiod (CC) Fusion
- Medial Column Fusion
- Arthrodesis of the first metatarsophalangeal joint (MTP)

Substantial Equivalence:
All components of the subject system have been previously cleared under one of the following 510(k)s:

- K143717- Treace Medical Concepts(TMC) Plating System
- K153531- Treace Medical Concepts(TMC) Plating System

The purpose of this submission is solely to expand the indications of the TMC Plating System to include the use of the devices in pediatric patient populations, similar to the following two predicate plating systems:

- DePuy Orthopedics, Inc.: ALPS Small Fragment Plating System (K101240)
- Wright Medical Technology, Inc.: ORTHOLOC® 2.0/2.4 Plate & ORTHOLOC® 2 .0/2 .4 Screw (K090692)

The subject components were demonstrated to be substantially equivalent with respect to indications for use, design, dimension, and materials to the previously listed predicate devices.

Performance Testing:
Performance testing was not required to support the expanded indications for the subject device.