



Food and Drug Administration
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January 7, 2016

Treace Medical Concepts, Incorporated
% Ms. Kimberly Strohkirch
Managing Partner
Memphis Regulatory Consulting, LLC
3416 Roxee Run Cove
Bartlett, Tennessee 38133

Re: K153531

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: December 8, 2015
Received: December 9, 2015

Dear Ms. Strohkirch:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K153531

Device Name

Tracec 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. 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
 - Intercuneiform Fusions
 - Navicular-Cuneiform (NC) Fusion
 - Talo-Navicular (TN) Fusion
 - Calcaneo-Cuboid (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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary
Treace Medical Concepts (TMC) Plating System
December 8, 2015

Company: Treace Medical Concepts, Inc.
3107 Sawgrass Village Circle
Ponte Vedra Beach, FL 32082

Primary Contact: Kimberly Strohkirch
Phone: (901) 361-2037
Fax: 904.834.7169
Strohkirch@memphisregulatory.com

Company/Secondary Contact: Joe Ferguson, Chief Operating Officer
Phone: 904.373.5840 Ext. 303
Fax: 904.834.7169
jferguson@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
HWC

Device Description:

The Treace Medical Concepts (TMC) Plating System includes a curved PYTHON™ plate to accommodate the tarso-metatarsal (TMT) joint, which is an indication of the TMC Plating System. The plate is available in both right and left configurations and is used with compatible 2.5 mm diameter screws in lengths ranging from 10-28 mm. 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).

Indications for Use:

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 - Intercuneiform Fusions
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 - Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion
- Arthrodesis of the first metatarsophalangeal joint (MTP)

Substantial Equivalence:

The subject PYTHON™ plate of the TMC Plating System components is identical to the predicate device with respect to indications for use, design, dimension, and materials to the following device, previously cleared by the FDA:

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

As indicated above, there are insignificant differences between the subject and predicate devices. The PYTHON™ plate does not present a new worst-case to the TMC plating system. The subject device includes all of the same indications as the predicates. Thus, the subject PYTHON™ plate is substantially equivalent to the predicate TMC Plating System.

Performance Testing:

Mechanical testing, includes dynamic 4-point bend testing has been performed per ASTM F382 on the subject PYTHON™ plate of the TMC Plating System and the results have confirmed them to be substantially equivalent to the predicate devices of the TMC Plating System.