



Food and Drug Administration
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March 19, 2015

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

Re: K143717

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: March 2, 2015
Received: March 3, 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" (21CFR 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)

K143717

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
February 27, 2015

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

Primary Contact: Kimberly Strohkirch
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Company/Secondary Contact: Joe Ferguson, Chief Operating Officer
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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 straight, L-shaped, and H- shaped 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. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI).

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. 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)

Substantial Equivalence:

The subject TMC Plating System components were demonstrated to be substantially equivalent with respect to indications for use, design, dimension, and materials to the following devices, previously cleared by the FDA:

- DePuy (Biomet): ALPS Small Fragment Plating System- K081546
- Wright Medical Technology, Inc.: Ortholoc™ 3Di Foot Reconstruction Midfoot/Flatfoot System- K121651
- Wright Medical Technology, Inc.: Ortholoc™ 3Di Hallux System- K120359
- Wright Medical Technology, Inc.: Ortholoc™ ORTHOLOC® 2.0/2.4 Plate & ORTHOLOC® 2.0/2.4 Screw- K090692

As indicated above, there are insignificant differences between the subject and predicate devices. The subject device includes all of the same indications as the predicates. The 2.5mm locking screws fall within the size range of those previously cleared by the predicates. Additionally, the subject 4-hole and 5-hole straight plates fall within the lengths of the previously cleared devices, differing only slightly in width and thickness. The subject H-plate is similar in design to the

WMT Ortholoc™ U plate in design, with added “arms” for additional stabilization and fixation. The subject L-plate is similar to the previously cleared L-plates, differing in degree at which the “L-arm” protrudes. The subject L-plate forms a 90 degree angle, while the predicate device angles are slightly larger.

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 TMC Plating System and the results have shown them to be substantially equivalent to the predicate devices.