



Treace Medical Concepts, Inc.
% Dawn Norman
Executive Vice President
MRC|X, LLC.
203 Fort Wade Rd., Suite 150
Ponte Vedra, Florida 32081

March 19, 2018

Re: K173930

Trade/Device Name: PYTHON Plate Trial Instruments
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: February 19, 2018
Received: February 20, 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. 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.

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.

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,

Katherine D. Kavlock -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)

K173930

Device Name

PYTHON Plate Trial Instruments

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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510(k) Summary*PYTHON® Plate Trial Instruments**December 22, 2017*

Company: Treace Medical Concepts, Inc.
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Trade Name: **PYTHON Plate Trial Instruments**

Common Name: Plate, Fixation, Bone

Classification: Class II

Regulation Number: 21 CFR 888.3030 (Single/Multiple Component Metallic Bone Fixation Appliances and Accessories)

Panel: 87- Orthopedic

Product Code: HRS

Device Description:

The previously cleared Treace Medical Concepts, Inc (TMC) Plating System includes the PYTHON® plate. The PYTHON® Plate is a curved plate available in both left and right configurations. The plate is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet.

This submission adds re-usable device specific trial instruments as Class II Instruments (the subject device) to this system. The trial instruments are manufactured from Titanium alloy conforming to ASTM F136.

Indications for Use:

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- 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
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 - 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 PYTHON® Plate Trial Instrument components were demonstrated to be substantially equivalent with respect to indications for use, design, dimension, and materials to the following device, previously cleared by the FDA:

- Treace Medical Concepts, Inc (TMC) Plating System- PYTHON® Plate (K153531)

The intended use and indications for use, material and overall geometry for the predicate device is identical to those of the subject device. As the subject device is a trial instrument, and is not intended for implantation, it has additional attached drill guides that can be used to replace the modular drill guides which were cleared with the predicate implant. These drill guides allow bone preparation to be performed through the trial instrument and do not raise new questions about safety and effectiveness.

Performance Testing:

Engineering analysis has confirmed the subject instruments to be substantially equivalent to the predicate PYTHON® Plates.