Treace Medical Concepts, Inc.
% Dawn Norman
Executive Vice President
MRC/X
6075 Poplar Avenue, Suite 500
Memphis, Tennessee 38119

October 25, 2017

Re: K172617
Trade/Device Name: Treace Medical Concepts (TMC) Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 30, 2017
Received: August 31, 2017

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.

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 (DICE) 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 (DICE) 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,

Mark N. Melkerson -S

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. 0910-120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172617

Device Name
Treace Medical Concepts (TMC) Compression Screw System

Indications for Use *(Describe)*
The Treace Medical Concepts (TMC) Compression Screw System is intended for use for adult and pediatric patients, as indicated for small or long bones requiring fixation of fractures, fracture repair, revision procedures, joint fusions (arthrodesis), bone reconstructions, osteotomy, ligament fixation, and pseudoarthrosis (non-unions) of bones, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, phalanges, patella, ulnar styloid, capitellum, radial head and radial styloid.

In the foot, the following specific examples are indicated with screws appropriate for the size of the device:
- mono or bicortical osteotomies
- distal or proximal metatarsal osteotomies
- weil osteotomy
- fusion of the metatarsalphalangeal joint
- fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
- Akin type osteotomy
- talonavicular fusions
- cuboid fusions

Not for spinal use.

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

K172617 510(k) Summary
Treace Medical Concepts (TMC) Compression Screw System
September 29, 2017

Company: Treace Medical Concepts, Inc.
203 Fort Wade Road, Suite 150,
Ponte Vedra, FL 32081

Establishment Registration: 3011623994

Primary Contact: Dawn Norman
Phone: 618.604.3064
Fax: 904.834.7169
Email: dawn.norman@mrc-x.com

Company/ Secondary Contact: Rachel Osbeck, Sr. Director, Quality Assurance
Phone: 904.373.5940 Ext. 304
Fax: 904.834.7169
Email: rosbeck@treace.net

Trade Name: **Treace Medical Concepts (TMC) Compression Screw System**

Common Name: Screw, Fixation, Bone

Classification: Class II

Regulation Number: 21 CFR 888.3040 (Smooth or Threaded Metallic Bone Fixation Fastener)

Panel: 87 – Orthopedic

Product Code: HWC

Predicate Devices:

Primary Predicate:
- I.T.S. Extremity Fixation Systems (K131722)

Additional Predicates:
- Apogee OrthoSolutions, LLC Monster Screw System™ (K124027)
- Smith & Nephew Cannulated Screws and Washers (K111994)

Reference Device:
- Treace Medical Plate System (K143717)

Device Description:

The Treace Medical Concepts (TMC) Compression Screw System includes headed and headless cannulated screws, lengths 10mm-100mm (2mm increments up to 50mm, then 5mm increments). The diameters are 2.0mm to 7.5mm (in 0.5mm increments) and 3.3mm. The TMC Compression Screw System is intended for use for adult and pediatric patients, as indicated for small or long bones requiring fixation of fractures, fracture repair, revision procedures, joint fusions (arthrodesis), bone reconstructions, osteotomy, ligament fixation, and pseudoarthrosis (non-unions) of bones, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, phalanges, patella, ulnar styloid, capitellum, radial head and radial styloid, appropriate for the size of the device. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI; hereafter called Ti-6-4) and anodized.

Indications for Use:

The TMC Compression Screw System is intended for use for adult and pediatric patients, as indicated for small or long bones requiring fixation of fractures, fracture repair, revision procedures, joint fusions (arthrodesis), bone reconstructions, osteotomy, ligament fixation, and pseudoarthrosis (non-unions) of bones, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, phalanges, patella, ulnar styloid, capitellum, radial head and radial styloid.
In the foot, the following specific examples are indicated with screws appropriate for the size of the device:

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- Akin type osteotomy
- talonavicular fusions
- cuboid fusions

Not for spinal use.

Substantial Equivalence:

The intended use and indications for use of the subject devices are substantially equivalent to the predicate devices. The materials of construction of the subject devices are equivalent to the predicate devices and the exact same materials and processing as that of the reference device. The dimensions of the subject devices are equivalent to the dimensions of the predicate devices. Thus, the subject devices are substantially equivalent to the predicate devices.

Performance Testing:

Performance bench testing per ASTM F543-13 was conducted on the worst-case construct of the subject devices. Sterilization validation has been completed per ISO 11137-2:2006 and endotoxin testing completed per AAMI ST72:2002/R2010. Therefore, the subject devices are substantially equivalent to the predicate devices.