October 21, 2021

Treace Medical Concepts, Inc.
% Danielle Besal
Principal Consultant
MRC Global, LLC
9085 E Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K213036
Trade/Device Name: Treace Medical Concepts (TMC) Screw Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 20, 2021
Received: September 21, 2021

Dear Danielle Besal:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213036

Device Name
Treace Medical Concepts (TMC) Screw Fixation System

Indications for Use *(Describe)*
The Treace Medical Concepts (TMC) Screw Fixation System is intended for use for adult and pediatric patients aged >12 years, and 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.

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510(k) Summary

Treace Medical Concepts (TMC) Screw Fixation System

October 21, 2021

Company: Treace Medical Concepts, Inc.
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Ponte Vedra, FL 32081

Primary Contact: Danielle Besal
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Regulatory Affairs Director
Treace Medical Concepts, Inc.
Phone: 904.373.5940
khall@treace.net

Trade Name:	**Treace Medical Concepts (TMC) Screw Fixation 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
Primary Predicate:	K172617 TMC Compression Screw System

Device Description:

Treace Medical Concepts (TMC) Screw Fixation System includes headed and headless cannulated screws. The TMC Screw Fixation System is intended for use for adult and pediatric patients aged >12 years, and 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.

The purpose of this special 510(k) submission is to add a new non-cannulated screw option known as the Rapid Insertion Implant System.

All implantable components are manufactured from medical grade titanium alloy (Ti-6Al-4V-ELI) per ASTM F136 and are provided sterile by gamma irradiation.

Indications for Use:
The Treace Medical Concepts (TMC) Screw Fixation System is intended for use for adult and pediatric patients aged >12 years, and 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.

Substantial Equivalence:
The subject TMC Screw Fixation System is substantially equivalent to the predicate Treace Medical Concepts (TMC) Compression Screw System (K172617).

The subject screws are manufactured from titanium (Ti-6Al-4V-ELI) and are intended to be used in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet, identical to the predicate devices. Indications for use have been slightly modified to very clearly state the age range of the patient population. The patient population has not changed. The subject screws also share similar geometry and construction with the predicate.

Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:
The following performance testing has been completed in accordance with ASTM F543:

- Torque To Failure and Insertion & Removal Torque
- Axial Pullout – Driver Disengagement
- Axial Pullout – Bone Screw Disengagement

Testing demonstrated that the subject screws met all acceptance criteria and can be considered substantially equivalent to the predicate screws.

Conclusion:

The Treace Medical Concepts (TMC) Screw Fixation System has identical intended use, similarities in design and construction, and equivalent performance to the predicate device as demonstrated through bench testing and engineering analysis. Therefore, it can be concluded that the subject device is as safe, as effective, and performs at least as safely and effectively as the predicate device.