November 15, 2022

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

Re: K222564
Trade/Device Name: Treace Medical Concepts (TMC) Hammertoe 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: August 24, 2022
Received: August 24, 2022

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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*

K222564

Device Name

Treace Medical Concepts (TMC) Hammertoe Fixation System

Indications for Use *(Describe)*

The TMC Hammertoe Fixation System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. Cannulated implants in the TMC Hammertoe Fixation System can be used with K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

The Implantable K-Wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, Implantable K-Wires are indicated for the fixation of osteotomies and reconstruction of the lesser toe following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal joint instability.

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.

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510(k) Summary
Treace Medical Concepts (TMC) Plating System
August 24, 2022

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

Primary Contact: Danielle Besal
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Company/Secondary Contact: Kristina Hall
Director, Regulatory Affairs
Treace Medical Concepts, LLC
Phone: 904-373-5940
khall@treace.net

Trade Name: Treace Medical Concepts (TMC) Hammertoe Fixation System

Common Name: Screw, Fixation, Bone

Classification: Class II

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

Panel: Orthopedic

Product Code: HWC

Primary Predicate: K132912 In2Bones SAS, Duafit® interphalangeal implant

Additional Predicate: K140148, Wright Medical Technology Inc., PRO-TOE® Hammertoe Fixation System

Device Description:
The Treace Medical Concepts (TMC) Hammertoe Fixation System is for the fixation of osteotomies and reconstruction of the lesser toes. The cannulated implant is made of PEEK (Polyetheretherketone) according to ASTM F2026 and is available in different sizes. The implants are delivered sterile packaged and for single use only.

The Implantable K-wire is made from stainless steel according to ASTM F138 and available in different sizes. The k-wire is delivered sterile packaged and for single use only.

All implantable components are provided sterile by gamma irradiation.

Indications for Use:
The TMC Hammertoe Fixation System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. Cannulated implants in the TMC Hammertoe Fixation System can be used with K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g., MTP Joint).

The Implantable K-Wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, Implantable K-Wires are indicated for the fixation of osteotomies and reconstruction of the lesser toe following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal joint instability.

Substantial Equivalence:
The subject TMC Hammertoe Fixation System is substantially equivalent to the predicate In2Bones SAS, Duafit® interphalangeal implant (K132912) and Wright Medical Technology Inc., PRO-TOE® Hammertoe Fixation System (K140148).

The subject device, TMC Hammertoe Fixation System, is comprised of polyetheretherketone (PEEK) implant, stainless steel k-wires for implantation, and stainless steel bone preparation instruments. The system is provided sterile by gamma irradiation. The PEEK implant is manufactured according to the surgical specification requirements of ASTM F2026. The implantable k-wires are made from stainless steel according to ASTM F138.

The components are equivalent in intended use, indication for use, geometry, design, materials, and mechanical performance. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

The TMC Hammertoe Fixation System geometry, materials, and mechanical properties (Static and Dynamic Four-Point Bending per ASTM F382-17, Annex A1 and A2, Axial Pullout per ASTM F543-17, Annex A3, Static Torsion per ASTM F543-17, Annex A1, and Driving Insertion and Removal Torque per ASTM F543-17, Annex A2,) have been evaluated to confirm substantial equivalence to the predicate devices.

Conclusion:

The subject TMC Plating System is substantially equivalent to the predicates, In2Bones SAS, Duafit® interphalangeal implant (K132912) and Wright Medical Technology Inc., PRO-TOE® Hammertoe Fixation System (K140148).