September 15, 2026

Treace Medical Concepts, Inc.
Melissa Coloroso
Principal Regulatory Affairs Specialist
100 Palmetto Park Pl.
Ponte Vedra, Florida 32081

Re: K262963
Trade/Device Name: TMC Implant Fixation 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, JDR, HWC
Dated: August 24, 2026
Received: August 25, 2026

Dear Melissa Coloroso:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262963

Please provide the device trade name(s).

TMC Implant Fixation System

Please provide your Indications for Use below.

The TMC Implant Fixation System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of the feet. The system can be used in pediatric (aged >12 years-21) and adult (aged 22 and over) patients. In the foot, the system can be used for the following specific examples:
•Osteotomy of the 1st and/or 5th Metatarsals for the treatment of deformity (e.g., hallux valgus,hallux rigidus, hallux limitus, tailor's bunion) such as:
- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic osteotomy
- Proximal Chevron osteotomy
- Distal Chevron osteotomy (Austin)
- Transverse osteotomy
•Arthrodesis of the tarsometatarsal (TMT) joints or the 1st metatarsophalangeal (MTP) joint for the treatment of deformity (e.g., hallux valgus, hallux rigidus, metatarsus adductus) and/or arthritis
•First metatarsal fracture fixation
•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
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary
Treace Medical Concepts (TMC) Medical Concepts Implant Fixation System
September 09, 2026

Company:	Treace Medical Concepts, Inc. 100 Palmetto Park Place Ponte Vedra, FL 32081
Establishment Registration:	3011623994
Primary Contact:	Melissa Coloroso, Principal Regulatory Affairs Specialist Phone: 303-641-8592 Fax: 904-834-7169 Email: mcoloroso@treace.net
Secondary Contact:	Kristina Hall, Sr. Director, Regulatory Affairs Phone: 904-373-5940 ext. 1321 Fax: 904-834-7169 Email: khall@treace.net
Trade Name:	Treace Medical Concepts (TMC) Implant Fixation System
Common Name:	Primary: Plate, fixation, bone Subsequent: Staple, fixation, bone; Screw, fixation, bone
Classification:	Class II
Regulation Number:	21 CFR 888.3030 21 CFR 888.3040
Panel:	87- Orthopedic
Product Code(s):	Primary: HRS Subsequent: JDR, HWC

Predicate Device(s):
Primary Predicate:

- Treace Medical Concepts (TMC) Implant Fixation System (K251135, S.E. 08/21/2025)

Additional Predicates:

- Wright Medical Technology Inc., PROSTEP™ TBI™ (Tailors Bunion Implant) System (K190970, S.E. 08/13/2019)

Device Description:
Treace Medical Concepts (TMC) Implant Fixation System includes straight, L-shaped, H-shaped, anatomically curved plates, intramedullary plates, cannulated and non-cannulated compression implants, and associated instruments. It includes 2.5 mm, 2.7 mm, 3.0 mm and 3.3 mm diameter cannulated and non-cannulated, locking, and non-locking screws in lengths ranging from 10-36 mm. All implantable components are manufactured from implant grade titanium alloy (Ti6Al4V-ELI) per ASTM F136 and are provided sterile by gamma irradiation.

The changes described within this submission do not impact reprocessing, biocompatibility and sterility considerations in comparison to the predicate devices. The software, cybersecurity, EMC, and wireless technology sections are not applicable to the subject device.

Indications for Use:
The TMC Implant Fixation System is intended for use for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of the feet. The system can be used in pediatric (aged >12 years-21) and adult (aged 22 and over) patients. In the foot, the system can be used for the following specific examples:

•Osteotomy of the 1st and/or 5th Metatarsals for the treatment of deformity (e.g., hallux valgus, hallux rigidus, hallux limitus, tailor's bunion) such as:
- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic osteotomy
- Proximal Chevron osteotomy
- Distal Chevron osteotomy (Austin)
- Transverse osteotomy

•Arthrodesis of the tarsometatarsal (TMT) joints or the 1st metatarsophalangeal (MTP) joint for the treatment of deformity (e.g., hallux valgus, hallux rigidus, metatarsus adductus) and / or arthritis
- First metatarsal fracture fixation

•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
  - Intercuneiform Fusions
  - Navicular-Cuneiform (NC) Fusion
  - Talo-Navicular (TN) Fusion
  - Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion

Substantial Equivalence:
The primary predicate, the Treace Medical Concepts (TMC) Implant Fixation System (K251135, S.E. 08/21/2025), provides substantial equivalence to the subject TMC Implant Fixation System regarding identical intended use, materials, packaging, and similar overall design. The subject TMC Implant Fixation System is substantially equivalent to the additional predicate the PROSTEP™ TBI™ (Tailors Bunion Implant) System (K190970, S.E. 08/13/2019) given similar intended use, technology, materials, and mechanical performance.

The subject and predicate device are manufactured from implant grade titanium alloy (Ti6Al4V-ELI) per ASTM F136 and are intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of the feet. The technological differences between the subject and predicate devices include geometric modifications. Compared to the additional predicate, the subject device differs because it contains a cannulated and threaded intramedullary post. Any differences in the technological characteristics of the subject device when compared to

the predicate devices do not raise any new questions of safety and effectiveness. Thus, it can be concluded that the subject device is substantially equivalent to the predicate device.

Performance Testing:
Mechanical construct testing and analysis including static and dynamic 4-point bend testing and static torsion, driving torque, removal torque, and axial pullout engineering analysis based on ASTM F382 and ASTM F543 were performed between the subject and predicate plating systems. Further, engineering analysis of the worst-case cross-sections and geometries on the subject and predicate devices was performed. The mechanical testing, engineering analysis, cross-sectional, and geometrical analysis demonstrated that the subject devices did not present a new worst-case with regards to mechanical performance per ASTM F382 and ASTM F543 when compared to their predicate devices. The subject devices are substantially equivalent to the predicate devices.

Conclusion:
The subject Treace Medical Concepts (TMC) Implant Fixation System has similar intended use, overall design, materials and mechanical properties to the predicate devices as demonstrated through bench testing and engineering analysis. Therefore, it can be concluded that the subject devices are at least safe and effective as and are substantially equivalent to the predicate devices.