March 6, 2026

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

Re: K260361
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: February 4, 2026
Received: February 4, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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.	K260361

Please provide the device trade name(s).

Treace Medical Concepts (TMC) Screw Fixation System

Please provide your Indications for Use below.

The TMC Screw Fixation System is intended for primary and revision fracture fixation and repair, joint fusions (arthrodesis), bone reconstructions, osteotomies, pseudoarthroses (non-unions), and ligament fixation. The System is indicated for use in adult and pediatric patients > 12 years of age at the following anatomical sites:

- Upper extremity: glenoid, humerus, ulna, radius, and hand
- Lower extremity: tibia, fibula, patella, ankle, and foot. Indicated procedures include:

o Fusions (e.g., talocalcaneal, talonavicular, naviculocuneiform, calcanealcuboid, tarsometatarsal, metatarsophalangeal, and interphalangeal)

o Mono or bi-cortical osteotomies of the tarsals, metatarsals, and phalanges (e.g., Scarf, Chevron, Akin, Weil, and Transverse osteotomies for hallux valgus, tailor's bunion, metatarsus adductus, flatfoot, and hammertoe deformities).

Please select the types of uses (select one or both, as applicable).	☒ 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 Screw Fixation System
March 05, 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) 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(s):	HWC

Predicate Device(s):
Primary Predicate:
Treace Medical Concepts (TMC) Screw Fixation System (K242671, S.E. 10/04/2024)

Additional Predicates:
Arthrex Inc., Arthrex Compression FT Screws (K201132, S.E. 07/27/2020)
Skeletal Dynamics, REDUCT™ Headless Compression Screw System
(K143624, S.E. 01/13/2015)

Device Description:
Treace Medical Concepts (TMC) Screw Fixation System includes headed and headless, cannulated and non-cannulated screws. The TMC Screw Fixation System is intended for use for adult and pediatric patients aged >12 years. The TMC Screw Fixation System is intended for primary and revision fracture fixation and repair, joint fusions (arthrodesis), bone reconstructions, osteotomies, pseudoarthroses (non-unions), and ligament fixation.e.

All implantable components are manufactured from implant grade titanium alloy (Ti6Al4V-ELI) per ASTM F136 and are provided sterile by gamma irradiation.

The primary purpose of this Special 510(k) submission is to introduce additional screw fixation options and accompanying instrumentation within the Treace Medical Concepts (TMC) Screw

Fixation System. Secondly, a supplementary packaging configuration and labeling modifications are being incorporated within the system. Lastly, Treace is providing the Agency notification regarding minor modifications implemented for the TMC Screw Fixation System via internal documentation.

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 Screw Fixation System is intended for primary and revision fracture fixation and repair, joint fusions (arthrodesis), bone reconstructions, osteotomies, pseudoarthroses (non-unions), and ligament fixation. The System is indicated for use in adult and pediatric patients > 12 years of age at the following anatomical sites:

- Upper extremity: glenoid, humerus, ulna, radius, and hand
- Lower extremity: tibia, fibula, patella, ankle, and foot. Indicated procedures include:
  - Fusions (e.g., talocalcaneal, talonavicular, naviculocuneiform, calcanealcuboid, tarsometatarsal, metatarsophalangeal, and interphalangeal)
  - Mono or bi-cortical osteotomies of the tarsals, metatarsals, and phalanges (e.g., Scarf, Chevron, Akin, Weil, and Transverse osteotomies for hallux valgus, tailor's bunion, metatarsus adductus, flatfoot, and hammertoe deformities).

Substantial Equivalence:
The subject TMC Screw Fixation System is substantially equivalent to the predicate devices. The subject screws are manufactured from implant grade titanium alloy (Ti6Al4V-ELI) per ASTM F136 and is intended for use for adult and pediatric patients aged >12 years. The TMC Screw Fixation System is intended for primary and revision fracture fixation and repair, joint fusions (arthrodesis), bone reconstructions, osteotomies, pseudoarthroses (non-unions), and ligament fixation.

The subject TMC Screw Fixation System shares identical materials and similar geometry, construction, and overall design with the predicate system. The technological differences between the subject and predicate devices include geometric modifications. Any differences in the technological characteristics of the subject device compared to the predicate device 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 testing and analysis per ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws were performed on the subject screws to evaluate torsional strength, driving and removal torque, and axial pullout strength. The subject devices met the performance criteria specified in the FDA Guidance "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway". Additionally, a biocompatibility evaluation of the subject screws leveraged equivalence in material and manufacturing to previously cleared implants (K242671, K251135). The sterilization and packaging validation for the new sterile packaging were conducted per ISO

11137-1 and -2 and ISO 11607-1 and -2. The subject screws met all acceptance criteria and are substantially equivalent to predicate screws.

Conclusion:
The subject Treace Medical Concepts (TMC) Screw Fixation System has similar intended use, design, and equivalent performance to predicate devices as demonstrated through bench testing and engineering analysis. Therefore, it can be concluded that the subject device is as safe and effective and substantially equivalent to predicate devices.