October 8, 2025

Extremity Medical, LLC
Mary Hoffman
Director of Quality Assurance and Regulatory Affairs
300 Interpace Parkway
Building A, 2nd Floor
Parsippany, New Jersey 07054

Re: K250536
Trade/Device Name: MetaFore Small 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: September 8, 2025
Received: September 8, 2025

Dear Mary Hoffman:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250536

Device Name

MetaFore Small Screw System

Indications for Use *(Describe)*

The MetaFore Small Screw System is indicated for the fixation of bone fractures and for bone reconstruction in hand and forefoot surgery.

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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Traditional 510(k) Summary:

MetaFore Small Screw System

Submitter	Extremity Medical, LLC 300 Interpace Parkway Building A, 2nd Floor Parsippany, NJ 07054
Contact Person	Mary Hoffman, MS Director, Quality Assurance and Regulatory Affairs Phone: (973) 588-8980 ext. 502 Email: mhoffman@extremitymedical.com
Date Prepared	October 6, 2025
Trade Name	MetaFore Small Screw System
Classification Name and Number	21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener
Product Code	HWC (Screw, fixation, bone)
Primary Predicate	K153182– Neosteo Self-Compressive Screws
Additional Predicates	K150772 – Neosteo Snap-Off Self Compressive Screws
Device Description	The MetaFore Small Screw System consists of implantable screws, and accessories for use in arthrodesis procedures of the hand and forefoot. The screws consist of 2.0mm solid snap-off, 2.5 and 3.0mm cannulated headless and 3.0 and 4.0mm cannulated beveled available in various overall lengths and thread lengths. The screws are manufactured from titanium alloy (Ti-6Al-4V ELI) and provided sterile-packed. The instruments are manufactured primarily from surgical grade stainless steel and titanium and provided non-sterile.
Indications for use	The MetaFore Small Screw System is indicated for the fixation of bone fractures and for bone reconstruction in hand and forefoot surgery.
Statement of Technological Comparison	The MetaFore Small Screw System and predicate devices are equivalent in terms of design, material, mechanical properties and indications for use. The subject and predicate devices are based on the following same technological elements:

	• Implants are used temporarily to fixate the bones that are being repaired/reconstructed. • Devices are made of the same material (Ti-6Al-4V ELI per ASTM F136)
Non-clinical Testing	Torsional strength and driving torque testing per ASTM F543 and engineering analysis of axial pullout strength per Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway demonstrated that the new screws do not introduce a new worse case in terms of strength.
Clinical Testing	No clinical testing was performed.
Conclusion	The Extremity Medical MetaFore Small Screw System is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, principles of operation, design, mechanical testing and engineering analysis.