May 7, 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: K251128
Trade/Device Name: Extremity Medical External 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: KTT
Dated: April 11, 2025
Received: April 11, 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,

Lixin Liu -S

Lixin Liu, Ph.D
Assistant Director
DHT6A: Division of Joint Arthroplasty 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.	K251128

Please provide the device trade name(s).

Extremity Medical External Fixation System

Please provide your Indications for Use below.

The Extremity Medical External Fixation System is indicated for adults and pediatric patients (2 years old and older) for treatment of:

- Open and closed fractures
- Osteotomies
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis, infected union, non-union, or malunion of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity (orthoplastic surgery)
- Joint arthrodesis
- Infected fractures
- Correction of segmental bony or soft tissue defects
- Management of comminuted intra-articular fractures
- Bone transport
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Charcot foot reconstruction
- Offloading and/or immobilization of ulcers and/or wounds of the foot and ankle
- Ankle distraction (arthrodiastasis)
- Septic fusion

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Special 510(k) Summary:

External Fixation 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	May 7, 2025
Trade Name	Extremity Medical External Fixation System
Classification Name and Number	21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories
Product Code	KTT (Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component)
Primary Predicate	K241563 – Extremity Medical External Fixation System
Additional Predicates	K201253– Smith & Nephew Ilizarov External Fixator K161417 – Depuy Synthes Maxframe Multi-Axial Correction System
Device Description	The Extremity Medical External Fixation System consists of three basic types of elements: bridge elements, connection elements and bone anchorage elements. The system is intended for use in a variety of applications including but not limited to Charcot foot reconstruction, open fracture fixation, joint arthrodesis, limb lengthening and bone transport. The assembly is made up of two or more circular rings that are connected by struts, rods or pillars to provide a framework for fixation. HA coated half pins and tensioned wires are then used to fixate and stabilize bones and joints. Bridge elements include rings, manufactured from anodized aluminum, in various types and sizes to accommodate varying patient anatomy. Connection elements, manufactured from stainless steel and anodized aluminum, include threaded rods, threaded pillars, rancho cube pillars available in multiple lengths and struts available in multiple sizes. Bone anchorage elements include wires and HA coated half pins, manufactured from stainless steel, available in multiple diameters and lengths. HA coated half pins are provided sterile packed while all other system components are provided non-sterile. All External Fixation components are for single use only.

Indications for use	The Extremity Medical External Fixation System is indicated for adults and pediatric patients (2 years old and older) for treatment of: • Open and closed fractures • Osteotomies • Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction • Pseudoarthrosis, infected union, non-union, or malunion of long bones • Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction • Correction of bony or soft tissue deformity (orthoplastic surgery) • Joint arthrodesis • Infected fractures • Correction of segmental bony or soft tissue defects • Management of comminuted intra-articular fractures • Bone transport • Revision procedures where other treatments or devices have been unsuccessful • Bone reconstruction procedures • Charcot foot reconstruction • Offloading and/or immobilization of ulcers and/or wounds of the foot and ankle • Ankle distraction (arthrodiastasis) • Septic fusion
Statement of Technological Comparison	The Extremity Medical External Fixation System and predicate devices are substantially equivalent in terms of design, material, mechanical properties and indications for use. The subject and predicate are based on the following same technological elements: • Implants (HA coated half pins) are used temporarily to stabilize bones and/or joints and are fixed to external ring components via hardware. • Connection elements (Threaded rods and Polyaxial struts) are used to connect rings to other rings. • All subject and predicate devices are made of the same materials (Stainless Steel, Hydroxyapatite (HA), Aluminum 6061-T6, and Plastic (Delrin, Radel)) and thus have equivalent mechanical properties. Key differences in design of the subject device compared to the predicate are as follows: • Subject Polyaxial Struts contain a locking ball joint (male connection) compared to a universal joint (female connection) for the predicate hexapod (dynamic) struts. • Subject Half Pins are HA coated compared to non-HA coated predicate Half Pins. • Subject Threaded rod size offerings contain a longer length than predicate threaded rod size offerings. These differences in design do not introduce different issues of safety or effectiveness.

Non-clinical Testing	The Extremity Medical External Fixation System components were compared to the predicates by engineering analysis and mechanical testing in accordance with ASTM F1541-17. The results of this analysis indicate that the Extremity Medical External Fixation System is substantially equivalent to predicate devices and does not introduce different issues of safety or effectiveness.
Clinical Testing	No clinical testing was performed.
Conclusion	The Extremity Medical External Fixation System is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, principles of operation, design, engineering analysis and mechanical testing.