May 29, 2024

Metric Medical Devices, Inc.
William Casey Fox
President
846 Silver Springs
Helotes, Texas 78023

Re: K240049
Trade/Device Name: LINK™ External Fixator
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: January 5, 2024
Received: January 8, 2024

Dear William Casey Fox:

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.

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, PhD
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

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)*

K240049

Device Name

LINK™ External Fixator

Indications for Use *(Describe)*

The LINK™ External Fixator is indicated for 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy and 3) adjunctive fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude LINK™ Bone Pin placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula and sternum.

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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510(k) Summary of Safety and Effectiveness

510(k) Summary As required by 21 CFR 807.92:

Name of Sponsor: Metric Medical Devices, Inc., 846 Silver Springs, Helotes, TX, 78023

Contact: William Casey Fox, Ph.D., P.E., President
Phone: 210-535-6300
e-mail: fox@metricmd.com

Date Prepared: 3/5/2024

Device Trade Name: LINK™ External Fixator

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Common Name: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

Device classification: Class II per 21 CFR 888.3030

Product Code: KTT

Predicate Device: Gexfix External Fixation (K160972, product code KTT)

Reference Devices: ORTHOFIX MODULSYSTEM (K955848, product code JDW) and Super Staple™ Classic (K123363, product code JDR)

Indications for use: 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy and 3) adjunctive fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude LINK™ bone pin placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula and sternum.

Device Description: The LINK™ External Fixator is a single use External Fixator consisting of a stainless steel flat spring formed into a box shape so that when released it applies forces and moments to Bone Pins, K-wires or Steinmann pins embedded in bone to actively pull together and compress or distract bone.

In clinical use the LINK™ External Fixator is held with its holes aligned using surgical needle drivers while wires or pins are advanced through the LINK™ External Fixator, skin and into bone. Once pins are placed the needle drivers are released, the LINK™ External Fixator

bridge shortens to apply forces and the LINK™'s side elements swing outward to create moments on the wires or pins.

The LINK™ External Fixator uses spring heat treated 17-7 stainless steel which is uniquely formed from a flat plate to create a shape changing spring. The Bone Pins in this kit are formed with 316 Stainless Steel. The LINK™ External Fixator has a separate removable silicon elastomer cover to protect the LINK™ External Fixator and the patient from the pin ends. Only the Bone Pins are in contact with the patient while the LINK™ External Fixator and its cover are external to the body and not intended for patient contact.

Comparison of Technical Characteristics with the Predicate Device:
The LINK™ External Fixator is substantially equivalent to legally marketed Gexfix External Fixation (K160972, product code KTT) in indications for use, material, design and function. Any minor differences between these devices or their performance do not raise any different questions of safety and effectiveness.

Parameter	LINK™ External Fixator	Gexfix External Fixation
Mode of Operation	Fixation with bone locking pins and room temperature implant shape change	Fixation with bone locking pins and room temperature shape change
Insertion	Wire/pin driver	Wire/pin driver
Pin, wire or implant Biomaterial	316 Stainless Steel	316 Stainless Steel
Fixator Biomaterial	17-7 Stainless Steel	Stainless Steel screws & aluminum rail
Implant Shape	Round wire/pin	Round wire/pin
Fixator Instruments	Stainless Steel Needle Divers	Stainless Steel integral knob
Principal of Operation	Shape changing spring acts on pins and wires.	Shape changing power screw and clamps act on pins and wires.

Biomechanics	Moments and forces created on wires and pins apply dynamic forces to bone. Compression can be achieved.	Forces created through power screw activation act on wires and pins to apply static forces to bone. Compression and distraction can be achieved.
Packaging	Sterile fixator, bone pins, and cover in Tyvek chevron pouches within a cardboard or plastic container	Metal or plastic sterilization tray
Sterilization	Gamma sterilized	Non-sterile; sterilized by end-user

Performance Data: Bench testing included construct pull out, 4-point bending for bone pin, 4-point bending for fixator construct in a bone analog, static ultimate strength in tension bending, fatigue in tension bending and the LINK™ force applied to bone.

Substantial Equivalence Conclusion

It is concluded that the LINK™ External Fixator and components are substantially equivalent to the predicate device cleared under K160972 and any minor differences between these devices or their performance do not raise any different questions of safety and effectiveness.