September 29, 2023

CrossRoads Extremity Systems
Keith Knapp
Regulatory Affairs Specialist
6423 Shelby View Dr., Suite 101
Memphis, Tennessee 38134

Re: K230591
Trade/Device Name: TRILEAP Plating 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, HWC
Dated: August 14, 2023
Received: August 23, 2023

Dear Keith Knapp:

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,

Tejen D. Soni -S

For
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230591

Device Name
TRILEAP Plating System

Indications for Use *(Describe)*
The TRILEAP™ Plating System is indicated for fixation of bones and bone fragments of the foot and ankle in adults and adolescents (aged 12 -21 years) where the growth plates have fused.

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.

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CrossRoads Extremity Systems

510(k) Summary

Sponsor	CrossRoads Extremity Systems, LLC Keith Knapp 6423 Shelby View Dr, Suite 101 Memphis, TN, 38134, USA Phone: +1-610-719-5942
Date Prepared	03/02/2023
Proprietary Name	TRILEAP Plating System
Device Common Name	Plate, Fixation, Bone Screw, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories. (Primary) Smooth or threaded metallic bone fixation fastener.
Classification	Class II Regulation Number: 21 CFR 888.3030 (Primary) & 888.3040 Product Code: HRS (Primary), HWC
Primary Predicate Devices	Synthes 2.4mm/2.7 mm Variable Angle LCP forefoot/ Midfoot System (K100776)
Additional Predicate Devices	MotoBAND™ CP Implant System: DynaBunion™ 4D Minimal-incision Bunion System, DynaMET™ Lesser TMT Fusion System (K223342)
Device Description	The TRILEAP Plating System is intended for reduction, temporary fixation, fusion and stabilization of bones. The system consists of a family of implantable devices consisting of 2.0mm, 2.5mm, 3.0mm, 3.5mm and 4.0mm non-contoured and anatomic procedure specific plates, cortical screws, and variable angle locking screws available in various sizes.
Indications for use	The TRILEAP™ Plating System is indicated for fixation of bones and bone fragments of the foot and ankle in adults and adolescents (aged 12 -21 years) where the growth plates have fused.
Non-clinical Performance Data	The following analyses were conducted for TRILEAP Plating System. Screw testing utilized acceptance criteria from the FDA Guidance, “Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway (December 2020)”. • Plate Cross-Section Analysis (Bending Strength) • Screw Torsional Strength Analysis according to ASTM F543 via a Finite Element Analysis model • Screw Driving Torque according to ASTM F543

CrossRoads™ Extremity Systems

	• Screw Pull-Out via the Chapman Equation
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	The proposed subject devices have the same intended uses as the predicate devices. The proposed subject devices share similar indications, are similar in design, material, and fundamental technology with the identified predicate devices. The testing and analytical evaluation included in this submission demonstrate that: • Any differences in technological characteristics of the predicate devices do not raise any new questions of safety and effectiveness • The proposed devices are at least as safe and effective as the predicate devices
Conclusion	In conclusion, the results of non-clinical performance data demonstrate that the subject devices are substantially equivalent with the predicate devices.