January 6, 2026

Crossroads Extremity Systems
Jacqueline Gorberg
Senior Regulatory Affairs Specialist
6423 Shelby View Dr.
Suite 101
Memphis, Tennessee 38134

Re: K253178
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: September 26, 2025
Received: September 26, 2025

Dear Jacqueline Gorberg:

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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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.	K253178

Please provide the device trade name(s).

TRILEAP Plating System

Please provide your Indications for Use below.

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.

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)

510(k) Summary - K253178

Applicant Name: CrossRoads Extremity Systems

Applicant Address: 6423 Shelby View Dr., Suite 101 Memphis TN 38134 United States

Applicant Contact Telephone: (267) 885-9690

Applicant Contact: Ms. Jacqueline Gorberg

Applicant Contact Email: jgorberg@its.jnj.com

Prepared On Date: December 19, 2025

Device Name

Device Trade Name: TRILEAP Plating System

Common Name: Plate, Fixation, Bone (Primary); Screw, Fixation, Bone

Classification Name: Single/multiple component metallic bone fixation appliances and accessories (Primary); Smooth or threaded metallic bone fixation fastener

Regulation Number: 21 CFR 888.3030 (Primary); 21 CFR 888.3040

Product Code: HRS (Primary); HWC

Legally Marketed Predicate Device

Predicate #: K230591

Predicate Trade Name: TRILEAP Plating System

Product Code: HRS (Primary); HWC

Device Description Summary

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, variable angle locking screws, and Jones screws available in various sizes. System implants are manufactured from titanium alloy and intended for single use only.

Instruments that may be used with the TRILEAP™ Plating System include Drill Guides, Drill Bits, Cannulated Reamers, Depth Gauges, Bending Pins, Screwdrivers and other instrumentation for general surgery. General instruments are manufactured from stainless steel, aluminum, silicone and plastic. Dedicated system organizational trays are for use in health care facilities for the purpose of containing and protecting medical devices during transportation and storage.

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 Summary

To demonstrate the safety and efficacy of the subject devices and support the substantial equivalence to their predicates, the following tests were performed:

- Plate 4-Point Bend – Testing demonstrated that subject plates were non-inferior regarding their bending strength and stiffness compared to predicate plates.
- Screw Torsional Strength – Testing demonstrated that subject Jones screws were non-inferior to predicate screws for torsional yield strength.
- Screw Driving Torque – Assessment in accordance with the FDA Guidance document, *Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway* demonstrated that the subject Jones screws met the performance criteria for driving torque and that no damage or deformation was observed in the bone screw thread geometry after test completion.
- Screw Axial Pull-out Strength – Engineering analysis and utilization of the Chapman equation demonstrated that subject Jones screws met or exceeded the criteria set forth in FDA Guidance document, *Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway*.

Additionally, Magnetic Resonance (MR) compatibility was evaluated to establish MR Conditional parameters for the entire TRILEAP Plating System (including subject and predicate devices cleared with K230591).

Clinical Performance Summary

Clinical testing was not necessary for the determination of substantial equivalence.

Substantial Equivalence

The subject devices have the same intended use and indications for use as the predicate devices. The subject devices are identical to the predicate devices in terms of fundamental technology, materials, and reprocessing methods. The devices differ in some aspects of design.

The non-clinical performance data and analytic evaluations included in this premarket notification demonstrate that any differences in technological characteristics of the subject devices compared to 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

It is concluded that the information provided demonstrates the substantial equivalence of the subject devices to their predicate devices.