August 19, 2019

CrossRoads Extemity Systems, LLC
% Theresa Leister
Senior Consultant
MRC-x, LLC
6075 Poplar Ave
Memphis, Tennessee 38119

Re: K191342
Trade/Device Name: CrossRoads 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: July 24, 2019
Received: July 25, 2019

Dear Theresa Leister:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, MPH
Assistant Director
DHT6C: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191342

Device Name
CrossRoads Screw System

Indications for Use *(Describe)*
The CrossRoads Screw System is indicated for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

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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510(k) Summary

CrossRoads Screw System

August 15, 2019

Company:	CrossRoads Extremity Systems, LLC 6055 Primacy Parkway, Suite 140 Memphis, TN 38119
Establishment Registration:	3011421599
Primary Contact:	Theresa Leister Phone: 901-489-1715
Company Contact:	Chad Hollis Phone: 901-221-8406
Trade Name:	CrossRoads Screw System
Common Name:	Screw, Fixation, Bone
Classification:	Class II
Regulation Number:	21 CFR 888.3040
Panel:	87- Orthopedic
Product Code:	HWC
Predicate Devices:	**Primary Predicate:** CrossRoads Screw System (K143039) **Secondary Predicate:** CrossRoads Screw System (K152072)

Device Description:

The CrossRoads Screw System was previously cleared under 510(k)s K143039 & K152072 and is comprised of bone screws having various features in a variety of diameters and lengths to accommodate differing patient anatomy. The screws that are the subject of this submission incorporate design modifications and additional lengths to the 2.0mm, 2.5mm, and 3.0mm screws as well as the addition of new 2.0mm, 4.0mm and 7.0mm Headless Screws. The design modifications include screw thread changes, screw head/driver interface changes, and the addition of reverse cutting threads.

Indications for Use:
The CrossRoads Screw System is indicated for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

Substantial Equivalence:
The subject CrossRoads Screw System components are substantially equivalent to the following predicate devices:

CrossRoads Screw System (K152072)

CrossRoads Screw System (K143039)

The subject components are similar to the predicate devices in terms of indications, geometry, and materials.

Performance Testing:

Engineering analysis was performed utilizing the worst-case sizes the subject CrossRoads Screw System. This analysis showed the subject device to be substantially equivalent in terms of performance to the predicate CrossRoads Screw System (K152072 and K143039). Thus, it was determined that no additional mechanical testing is required.

Conclusion:

There are no substantial differences between the CrossRoads Screw System and the predicate devices with respect to intended use and technological characteristics, including basic design, materials of manufacture, mechanical properties, and intended effect.

Therefore, the CrossRoads Screw System can be found substantially equivalent to the cited predicate, as it does not raise new questions of safety and effectiveness.