April 12, 2019

CrossRoads Extremity Systems, LLC
% Theresa Leister
Senior Consultant
Mrc-X, LLC
6075 Poplar Ave
Memphis, Tennessee 38119

Re: K190658
Trade/Device Name: MIS Bunion 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
Dated: March 6, 2019
Received: March 14, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K190658

Device Name
MIS Bunion Plating System

Indications for Use *(Describe)*
The MIS Bunion Plating System is intended for fixation of osteotomies and corrective procedures of the hallux and associated disorders such as hallux valgus.

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

MIS Bunion Plating System

March 6, 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: MIS Bunion Plating System

Common Name: Plate, Fixation, Bone

Classification: Class II

Regulation Number: 21 CFR 888.3030 (Single/multiple component metallic bone fixation appliances and accessories)

Panel: 87- Orthopedic

Product Code: HRS

Predicate Devices: CrossRoads Extremity Systems, LLC, MIS Bunion System (K181872)

Device Description:

The CrossRoads MIS Bunion System contains a buttressing implant which can be surgically implanted using a minimally invasive surgical technique to correct hallux valgus. The MIS Bunion implant is to be made of implant grade titanium (Ti-6Al-4V ELI) per ASTM F136 with features allowing it to accept a CrossRoads MotoBAND CP screw (previously cleared in K152306), the subject Ø3.0mm MIS Bunion locking screw, or the optional subject Ø2.7mm non-locking screw in the distal end of the implant. Instrumentation required for performing this surgery include a k-wire, for use with an osteotomy guide, osteotome guide and osteotome, a suture passing loop, drill bit and handle. Additional general surgical instrumentation utilized include reamers, drivers, drill guide/depth gauge. The MIS Bunion implant is tapered on the proximal end so that it can be easily inserted into the intramedullary canal of the metatarsal and the distal head of the implant will seat directly against the osteotomy surface. The MIS bunion implant wedges firmly within the intramedullary canal and acts as a buttress to hold the metatarsal head in place. To accommodate a range of anatomical sizes and severities of corrections, the

implant will be offered in an array of configurations; wherein each incremental size will increase in thickness on the distal end, resulting in different buttressing offsets. The tapered proximal end of the implant will also have interrupted surfaces to gain traction within the cancellous bone, thus resisting pullout. Finally, the MIS bunion implant will accept Ø3.0mm or Ø3.5mm CrossRoads MotoBAND CP screws (K152306) or the subject MIS Bunion Ø 3.0mm polyaxial locking screws in the most distal hole, in addition to the optional subject Ø2.7mm non-locking screw accepted only in the angular cross hole for additional fixation of the implant to the metatarsal shaft.

This Special 510(k) submission seeks to modify the design of the previously cleared plate to add an additional angular distal screw hole to accept optional placement of the subject Ø2.7mm non-locking screw for additional plate stability. Additionally, this submission seeks to expand the size range of the plates to include a shorter length plate to better accommodate patient anatomy.

Indications for Use:
The MIS Bunion Plating System is intended for fixation of osteotomies and corrective procedures of the hallux and associated disorders such as hallux valgus.

Substantial Equivalence:
The subject MIS Bunion System components are substantially equivalent to the following predicate devices to the previously cleared MIS Bunion System (K181872).

The subject components are identical to the predicate devices in terms of indications for use, materials, biocompatibility, and sterility. The only changes being made are the following design changes:

- Design changes to the MIS Bunion System buttressing plate to provide greater fixation and implant stability
- A shorter plate has been added for all plate configurations, to better accommodate patient anatomy.
- Ø2.7mm non-locking screws as well as Ø3.0mm polyaxial locking screws have been added to the system.

Mechanical analysis was performed on the subject design changes discussed above. This analysis verified that the design changes included in the subject devices do not present a new worst-case scenario. Thus, it can be concluded that the subject devices raise no new questions of safety and effectiveness and are substantially equivalent to the predicate devices.

Performance Testing:

Mechanical analysis was performed utilizing the worst-case cross sections the subject MIS Bunion System. This analysis showed the subject device to be substantially equivalent in terms of performance to the predicate MIS Bunion System. Thus, it was determined that no additional mechanical testing is required.

Additional mechanical analysis was performed on the subject MIS Bunion System screws. Screw pull through construct testing was also performed on the subject Ø3.0mm Locking Screw validating that the subject does not present a new worst case. All mechanical analysis performed showed the subject screws to be substantially equivalent in terms of performance to previously cleared Crossroads screws.

Conclusion:

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

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