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

August 9, 2018

Re: K181866
Trade/Device Name: MotoCLIP/HiMAX Step Staple Implant System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: July 11, 2018
Received: July 12, 2018

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,

Mark N. Melkerson -S

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)*
K181866

Device Name

MotoCLIP™/HiMAX™ Step Staple Implant System

Indications for Use *(Describe)*

The MotoCLIP™/HiMAX™ Step Staple Implant System is indicated for hand and foot bone fragment osteotomy fixation and joint arthrodesis.

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

MotoCLIP™/HiMAX™ Step Staple Implant System

July 29, 2018

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: MotoCLIP™/HiMAX™ Step Staple Implant System

Common Name: Staple, 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: JDR

Predicate Devices: CrossRoads CrossCLIP™ Staple (K142727)
CrossRoads MotoCLIP™/HiMAX Implant System (K181410)
Biomedical Enterprises, Speed Shift (K124022)

Device Description:

The MotoCLIP™/HiMAX™ Step Staple Implant System gives the surgeon a means of bone fixation in the management of bone fractures and reconstruction surgery. The MotoCLIP™/HiMAX™ Step Staple Implant System includes implants and the related instruments needed for implantation. The implants are made of nitinol. Prior to implantation, the legs of the implant are held substantially parallel to facilitate insertion into the prepared bone. Once implanted and released from the insertion device, the legs of the implant will move towards each other in a converging fashion. This movement creates compression across the adjoining bone members.

Indications for Use:
The MotoCLIP™/HiMAX™ Step Staple Implant System is indicated for hand and foot bone fragment osteotomy fixation and joint arthrodesis.

Substantial Equivalence:
The subject MotoCLIP™/HiMAX™ Step Staple Implant System components are substantially equivalent to the following predicate devices:

Primary Predicate: CrossRoads CrossCLIP™ Staple (K142727)
Additional Predicate: CrossRoads MotoCLIP™/HiMAX Implant System (K181410)
Biomedical Enterprises, Speed Shift (K124022)

The subject components are similar to the predicate devices in terms of indications, geometry, and materials. Mechanical analysis has shown the subject devices to be substantially equivalent in mechanical strength to the previously cleared CrossRoads CrossCLIP™ Staple (K142727). 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:

Finite element analysis was performed utilizing the worst-case sizes the subject MotoCLIP™/HiMAX™ Step Staple Implant System. This analysis showed the subject device to be substantially equivalent in terms of bending strength, bending stiffness, and pullout strength to the predicate CrossRoads CrossCLIP™ Staple (K142727).

Conclusion:

There are no substantial differences between the MotoCLIP™/HiMAX™ Step Staple Implant 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 MotoCLIP™/HiMAX™ Step Staple Implant System can be found substantially equivalent to the cited predicate, as it does not raise new questions of safety and effectiveness.