CrossRoads Extremity Systems, LLC
% Christine Seifert
Executive Vice President
MRC/X, LLC
6075 Poplar Avenue
Memphis, Tennessee 38119

June 29, 2018

Re: K181410
Trade/Device Name: MotoCLIP/HiMAX 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: May 25, 2018
Received: May 30, 2018

Dear Christine Seifert:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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)*
K181410

Device Name
MotoCLIP/HiMAX™ Implant System

Indications for Use *(Describe)*
The MotoCLIP™/HiMAX™ 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™ Implant System

June 24, 2018

Company: CrossRoads Extremity Systems, LLC
6055 Primacy Parkway, Suite 140
Memphis, TN 38119

Establishment Registration: 3011421599

Primary Contact: Christine Scifert
Phone: 901-831-8053

Company Contact: Chad Hollis
Phone: 901-221-8406

Trade Name: MotoCLIP™/HiMAX™ 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 Extremity Systems, LLC CrossCLIP™ Implants (K142727)

Device Description:

MotoCLIP™/HiMAX™ Implant System is a staple system which gives the surgeon a means of bone fixation in the management of bone fractures and reconstruction surgery. The MotoCLIP™/HiMAX™ Implant System is a line extension of the previously cleared CrossCLIP™ System K142727. After clearance, CrossRoads re-branded the CrossCLIP™ System to the MotoCLIP™™ Implant System.

The MotoCLIP™/HiMAX™ Implant System gives the surgeon a means for fixation of fractures, fusions, and osteotomies of the foot, ankle, and hand. The MotoCLIP™/HiMAX™ Implant System includes implants and the related instrumentation needed for implantation. The implants are made from implant grade Nitinol per ASTM F2063.

The only modifications being made in this submission are changes in the geometry of the implants and associated instruments.

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

Substantial Equivalence:
The subject MotoCLIP™/HiMAX™ Implant Sytem is substantially equivalent to CrossRoads Extremities Systems, LLC's previously cleared CrossCLIP™ Implant (K142727).

There are no substantial differences between the MotoCLIP™/HiMAX™ Implant System and the predicate CrossCLIP™ Implants (now branded MotoCLIP™/HiMAX™ Implant System) with respect to intended use and technological characteristics, including basic design, materials of manufacture, mechanical properties, and intended effect.

The minor modification that is the subject of this submission is that the geometry of the subject implants vary from the predicate implants. Engineering analysis shows that the performance of the implants meets or exceeds the strength of the worst-case implant in the previously cleared system (K142727).

Therefore, the MotoCLIP™/HiMAX™ Implant System can be found substantially equivalent to the cited predicate, as it does not raise new questions of safety and effectiveness.

Performance Testing:

Theoretical analysis (FEA) of the worst case MotoCLIP™/HiMAX™ Implant System was performed to predict compression force as well as maximum strain for the subject and predicate devices. In addition, pull-out testing was performed to compare the predicate to the subject device. The results of the theoretical analysis and pull-out testing demonstrate the predicted performance of the subject MotoCLIP™/HiMAX™ Implant System does not introduce a new worst case and therefore is substantially equivalent to the predicate devices.

Conclusion:

There are no substantial differences between the MotoCLIP™/HiMAX™ Implant System and the predicate CrossCLIP™ Implants (now branded MotoCLIP™/HiMAX™ Implant System) with respect to intended use and technological characteristics, including basic design, materials of manufacture, mechanical properties, and intended effect.

Therefore, the MotoCLIP™/HiMAX™ Implant System can be found substantially equivalent to the cited predicate, as it does not raise new questions of safety and effectiveness.