February 12, 2018

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

Re: K173710
Trade/Device Name: MotoBAND™ CP Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HRS
Dated: January 17, 2018
Received: January 18, 2018

Dear Ms. Scifert:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -S

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)*

K173710

Device Name
MotoBAND™ CP Implant System

Indications for Use *(Describe)*

The MotoBAND™ CP Implant System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. When used for these indications, the MotoBAND™ Implant System with the exception of the MTP plates and 2-hole plate may be used with the MotoCLIP™ Implant System.

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

Date:	February 8, 2018
Device Name:	*MotoBAND™ CP Implant System*
Company:	CrossRoads Extremity Systems (previously OrthoDiscovery Group LLC) 6055 Primacy Parkway, Suite 140 Memphis, TN 38119 USA Phone: 901.221.8406
Primary Contact:	Christine Scifert, MS, MEM Executive Vice President MRC-X, LLC 901-831-8053 christine.scifert@mrc-x.com
Company Contact:	Chad Hollis Vice President of Research & Development CrossRoads Extremity Systems 901.221.8406 chollis@crextremity.com
Trade Name:	*MotoBAND™ CP Implant System*
Common Name:	Plate System
Classification:	Class II
Regulation Number:	888.3040, Smooth or threaded metallic bone fixation fastener 888.3030, Single/multiple component metallic bone fixation appliances and accessories
Panel:	Orthopedic
Product Code:	HWC, HRS
Predicate Devices:	Primary Predicate: K160300 *MotoBAND™ CP Implant System*

	Additional Predicate: K152306 MotoBAND™ CP Implant System
Device Description:	The *MotoBAND™ CP Implant System* is comprised of implant plates and instruments, having various features and sizes to accommodate differing patient anatomy. Plate geometries include valgus options of 0˚, 5˚and 10˚, dorsiflexion options of 0˚, 2.5˚, 5˚, 7.5˚ and 10˚ and options to use either a 15mm or 18mm nitinol clip. *MotoBAND™ CP Implant System* is compatible with *MotoCLIP™ Staple.*
Indications for Use:	The MotoBAND™ CP Implant System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. When used for these indications, the MotoBAND™ CP Implant System with the exception of the MPJ plates and 2-hole plate may be used with the MotoCLIP™ Implant System.
Materials:	The *MotoBAND™ CP Implant System* implant components are manufactured titanium alloy (ASTM F136).
Substantial Equivalence:	Theoretical analysis of the worst case *MotoBAND™ CP Implant System* was performed to predict torsional and pullout strengths as well as plate bending strength for the subject and predicate devices (CrossRoads MotoBAND™ CP System K152306 and K160300). The results demonstrate the predicted performance of the *MotoBAND™ CP Implant System* is substantially equivalent to the predicate devices. There are no substantive differences between the *MotoBAND™ CP Implant System* and the cited predicates with respect to intended use and technological characteristics. The *MotoBAND™ CP Implant System* possesses the same technological characteristics as the predicate devices, including: • Predicted performance and method of stabilization, • Materials of manufacture, • Basic design, and • Mechanical properties.
Performance Testing:	Theoretical analysis of the worst case *MotoBAND™ CP Implant System* shows that the strength of the subject plates exceeds the strength of the worst-case plate in the predicate system (K152306 and K160300). The results demonstrate

the predicted performance of the *MotoBAND™ CP Implant System* is substantially equivalent to the predicate device.

Conclusion: The fundamental scientific technology of the MotoBAND™ CP Implant System devices is the same as previously cleared devices. Therefore, the MotoBAND™ CP Implant System is substantially equivalent for its intended use.