January 10, 2020

CrossRoads Extemity Systems, LLC
Kim Strohkirch
Sr. Director, QA/RA
6055 Primacy Pkwy, Suite 140
Memphis, Tennessee 38119

Re: K193452
Trade/Device Name: MotoBAND CP 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: HRS, HWC, JDR
Dated: December 12, 2019
Received: December 13, 2019

Dear Kim Strohkirch:

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: Division of 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)*

K193452

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 2-hole plate may be used with the MotoCLIP™/ HiMAX™ 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: January 9, 2019

Device Name: *MotoBAND™ CP Implant System*

Establishment Registration: 3011421599

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

Contact Person:
Kim Strohkirch
Sr. Director, QA/RA
CrossRoads Extremity Systems
901.221.8406
kstrohkirch@crextremity.com

Trade Name: *MotoBAND CP Implant System*

Common Name: Plate, Fixation, Bone

Classification: Class II

Regulation Number: 888.3030 Single/multiple component metallic bone fixation appliances and accessories

Panel: Orthopedic

Product Code:
HRS
HWC
JDR

Predicate Devices:
Primary Predicate:
K173710 MotoBAND CP Implant System

Additional Predicate:
K181410 MotoCLIP™/HiMAX™ Implant System

Device Description: The subject *MotoBAND CP Implant System* is comprised of implant plates and instruments, having various features and sizes to accommodate differing patient anatomy. Plate geometries are 5˚ valgus and have options of 0˚,5˚, and 10˚ dorsiflexion and can be used with 18mm, 20mm or 25mm nitinol clip. Non-locking and poly-axial locking screws are included in the system: 3.0mm diameter and 3.5mm diameters in lengths of 10-50 mm. *MotoBAND CP Implant System* is compatible with *MotoCLIP/HiMAX Clips.*

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™ Implant System, with the exception of the 2-hole plate, may be used with the MotoCLIP™/HiMAX™ Implant System.

Materials: The *MotoBAND CP Implant System* implant components are manufactured from titanium alloy (ASTM F136). MotoCLIP™/HIMAX™ *Implant System* is composed of nitinol.

Substantial Equivalence: Engineering analysis of the worst case *MotoBAND™ CP Implant System* was performed to compare component performance for the subject and predicate devices. Changes to the subject devices include 1. longer bridge length clips (20mm and 25mm) 2. longer length screws (32-50mm) and 3. plate geometry modification for clip compatibility. The maximum plate length decreased; the thickness and width are similar to the predicate plate. The results demonstrate the predicted performance of the *MotoBAND™ CP Implant System* with MotoCLIP™/HIMAX™ 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: Engineering analysis of the worst case *MotoBAND CP Implant System* with MotoCLIP™/HIMAX™ Implant System shows that the strength of the plates, staple bending strength and bending stiffness and staple/screw fixation performance exceeds the strength of the worst-case implants in the predicate system. No additional mechanical testing is required. The results demonstrate the performance of the subject *MotoBAND CP Implant System* is substantially equivalent to the predicate device.

Conclusion: There are no substantial differences between the *MotoBAND CP 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 *MotoBAND CP Implant System* can be found substantially equivalent to the cited predicate, as it does not raise new questions of safety and effectiveness.