March 30, 2023

CrossRoads Extremity Systems, LLC
Kim Strohkirch
Quality and Regulatory Leader
6423 Shelby View Dr., Suite 101
Memphis, Tennessee 38134

Re: K223342
Trade/Device Name: MotoBAND™ CP Implant System: DynaBunion™ 4D Minimal-incision Bunion System, DynaMET™ Lesser TMT Fusion 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: February 28, 2023
Received: March 1, 2023

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 -S

Shumaya Ali, M.P.H.
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223342

Device Name
MotoBAND™ CP Implant System: DynaBunion™ 4D Minimal-incision Bunion System and DynaMet™ Lesser TMT Fusion System

Indications for Use *(Describe)*
The MotoBAND™ CP Implant System includes DynaBunion™ 4D Minimal-incision Bunion System and DynaMet™ Lesser TMT Fusion System, which include plates and screws 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. DynaBunion™ 4D Minimal-incision Bunion System and DynaMet™ Lesser TMT Fusion plates are compatible with fracture fixation staples from the MotoCLIP™/HiMAX™ Implant System cleared in K142727, K181410 and K193452.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary**

| | |
|---|---|
| **Date:** | March 30, 2023 |
| **Device Name:** | *MotoBAND™ CP Implant System*<br>DynaBunion™ 4D Minimal-incision Bunion System<br>DynaMet™ Lesser TMT Fusion System |
| **Establishment Registration:** | 3020584246 |
| **Company:** | CrossRoads Extremity Systems, LLC<br>6423 Shelby View Dr., Suite 101<br>Memphis, TN 38134<br>UNITED STATES |
| **Contact Person:** | Kim Strohkirch<br>Quality & Regulatory Leader<br>CrossRoads Extremity Systems<br>901-664-5618<br>kstrohki@its.jnj.com<br><br>Secondary Contact:<br>Keith Knapp<br>Regulatory Affairs Specialist II<br>DePuy Synthes<br>610-719-5942<br>kknapp@its.jnj.com |
| **Trade Name:** | *MotoBAND™ CP Implant System* |
| **Common Name:** | Plate, Fixation, Bone<br>Screw, Fixation, Bone<br>Staple, Fixation, Bone |
| **Classification:** | Class II |
| **Regulation Number:** | 888.3030 Single/multiple component metallic bone fixation appliances and accessories (Primary)<br>888.3040 Smooth or threaded metallic bone fixation fastener |
| **Panel:** | Orthopedic |
| **Product Code:** | HRS |

HWC
JDR

**Predicate Devices:**

Primary Predicate:
K193452 MotoBAND CP Implant System
Additional Predicate:
K173710 MotoBAND CP Implant System

**Device Description:**

The subject devices branded as DynaBunion and DynaMet are additional plate configurations and screws being added to the predicate system, MotoBAND CP Implant System.

**DynaBunion™ 4D Minimal-incision Bunion System:**
The subject DynaBunion™ 4D Minimal-incision Bunion System includes the addition of the DynaBunion plates and screws to the MotoBAND CP Implant System. The Anti-Drift Bolt (ADB) is a modification of the MotoBAND CP Implant System screws for optional use with the subject DynaBunion plate to anchor the first metatarsal back to the base of the second metatarsal. DynaBunion instruments are used with the MotoBAND CP Implant System for the Lapidus procedure. The cut block and all associated instruments are Class I exempt instruments and may be used with previous versions of the MotoBAND CP Lapidus plates.

**DynaMet™ Lesser TMT Fusion System:**
The subject DynaMet™ Lesser TMT Fusion System includes the addition of the DynaMet staple compression plates (SCP) to the MotoBAND CP Implant System. The subject plates have 8 configurations with templates and are compatible with 15mm or 18mm HiMAX C staples. The subject plates are compatible with the same MotoBAND CP screws cleared in K193452. The DynaMET plates are a variation of plate designs for a specific application.

**Indications for Use**:

The MotoBAND™ CP Implant System includes DynaBunion™ 4D Minimal-incision Bunion System and DynaMet™ Lesser TMT Fusion System, which include plates and screws 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. DynaBunion™ 4D Minimal-incision Bunion System and DynaMet™ Lesser TMT Fusion plates are compatible with fracture fixation staples from the MotoCLIP™/HiMAX™ Implant System cleared in K142727, K181410 and K193452.

**Materials:**

Subject and predicate devices are manufactured from titanium alloy (ASTM F136).

**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 DynaBunion implants include 1. shorter and pre-contoured DynaBunion (Lapidus) plate 2. Oblique slot for the Anti-Drift Bolt and 3. Fully threaded and partially threaded Anti-Drift Bolt. Changes to the subject DynaMet implant include: 1. length is shorter than predicate and 2. Anti-drift bolt compatibility. Engineering analysis demonstrated that the dimensional differences do not create a new worst-case for the system. The dimensions are within previously plates of the MotoBAND family.

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 subject and predicate 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 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 subject and predicate devices with respect to intended use and technological characteristics, including basic design, materials of manufacture, mechanical properties, and intended effect.

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