



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

CrossRoads Extremity Systems, LLC
Mr. Vernon Hartdegen
Sr. Vice President of Operations
6055 Primacy Pkwy, Suite 140
Memphis, Tennessee 38119

December 11, 2015

Re: K152306

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

Dated: October 21, 2015

Received: October 26, 2015

Dear Mr. Hartdegen:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152306 (page 1 of 1)

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Date:	October 21, 2015
Device Name:	<i>MotoBAND™ CP Implant System</i>
Company:	CrossRoads Extremity Systems (previously OrthoDiscovery Group LLC) 6055 Primacy Parkway, Suite 140 Memphis, TN 38119 USA Phone: 901.221.8406
Primary Contact:	Vernon Hartdegen, Sr. VP of Operations 901.221.8406 Vhartdegen@crextremity.com
Trade Name:	<i>MotoBAND™ CP Implant System</i>
Common Name:	Plate System
Classification:	Class II
Regulation Number:	888.3030 Single/multiple component metallic bone fixation appliances and accessories 888.3040, Smooth or threaded metallic bone fixation fastener
Panel:	Orthopedic
Product Code:	HRS, HWC
Predicate Devices:	K083447 ANCHORAGE™ CP K131657 and K123562 Flower Small and Medium Implant Set
Device Description:	The <i>MotoBAND™ CP Implant System</i> is comprised of implant plates, bone screws and instruments, having various features and sizes to accommodate differing patient anatomy. Plate geometries include the double Y plate, Y-plate, straight plate (2 hole, 4 hole and 5 hole) and MTP plate with 10° Valgus, 0° Dorsi-Flexion.
Indications for Use:	The <i>MotoBAND™ CP Implant System</i> 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.

Traditional 510(k): *MotoBAND™ CP*



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 (Flower Orthopedic plates (K131657 and K123562) ANCHORAGE™ CP (K083447) plates). 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.

Therefore, 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.

Performance Testing: 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. The results demonstrate the predicted performance of the *MotoBAND™ CP Implant System* is substantially equivalent to the predicate device