



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 Parkway Suite 140
Memphis, Tennessee 38119

September 23, 2015

Re: K152072

Trade/Device Name: CrossRoads Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 1, 2015
Received: September 3, 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 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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

K152072

Device Name

CrossRoads Screw System

Indications for Use (Describe)

The CrossRoads Screw System is indicated for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

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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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

Date: July 23, 2015

Device Name: CrossRoads Screw System

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: CrossRoads Screw System

Common Name: Screw System

Classification: Class II

Regulation Number: 888.3040, Smooth or threaded metallic bone fixation fastener

Panel: Orthopedic

Product Code: HWC

Predicate Devices: K143039 CrossRoads Screw System
K000080 and K024060 Stryker Asnis III Screw System

Device Description: The CrossRoads Screw System is comprised of bone screws having various features in a variety of diameters and lengths to accommodate differing patient anatomy.

Indications for Use: The CrossRoads Screw System is indicated for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

Materials: The CrossRoads Screw System implant components are manufactured titanium alloy (ASTM F136) and stainless steel (ASTM F138).

Substantial Equivalence: Theoretical analysis of the worst case CrossRoads screws was performed to predict torsional and pullout strengths for the subject and predicate devices. The results demonstrate the predicted performance of the CrossRoads screws is substantially equivalent to the predicate devices. The CrossRoads Screw System possesses the same technological characteristics as the predicate devices. These include:

- predicted performance,
- implant grade materials, and
- basic design.

Therefore the fundamental scientific technology of the CrossRoads Screw System devices is the same as previously cleared devices. Therefore the CrossRoads Screw System is substantially equivalent for its intended use.

Performance Testing: Theoretical analysis of the worst case CrossRoads screws was performed to predict torsional and pullout strengths for the subject and predicate devices. The Large Screws do not result in a new worst-case within the system. The results demonstrate the predicted performance of the CrossRoads screws is substantially equivalent to the predicate devices.