



Food and Drug Administration
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CrossRoads Extremity Systems LLC
Mr. Vernon Hartdegen
Senior Vice President of Operations
6055 Primacy Parkway, Suite 140
Memphis, Tennessee 38119

September 4, 2015

Re: K151270

Trade/Device Name: CrossTie™ Intraosseous Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 12, 2015
Received: June 15, 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.

Page 2 – Mr. Vernon Hartdegen

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

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

Indications for Use

510(k) Number (if known)
K151270

Device Name

CrossTie™ Intraosseous Fixation System

Indications for Use (Describe)

The CrossTie™ Intraosseous Fixation System is indicated to aid in the fixation of fractures, fusions, and osteotomies of the toes, such as hammertoe, claw toe, mallet toe and inter-digital fusions.

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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Attachment 6

510(k) Summary CrossTie™ Intraosseous Fixation System

Date of Submission	September 3, 2015
Official Contact/Address of Manufacturing Facility	Vernon R Hartdegen Sr. Vice President of Operations CrossRoads Extremity Systems LLC 6055 Primacy Parkway, Suite 140 Memphis, TN 38119 Phone: 901-221-8406 Fax: n/a vhartdegen@crextremity.com
Proprietary Name	CrossTie™ Intraosseous Fixation System
Device Classification Name	Smooth or threaded metallic bone fixation fastener
Product Code	HWC
Classification Reference	21 CFR 888.3040
Classification	Class II
Appropriate Classification Panel	87 - Orthopedic
Predicate Devices	K141857 CrossTIE™ Intraosseous Fixation System
Reason For Submission	Update to Surgical Technique

Substantial Equivalence:

The modified fixation system has the following similarities to the previously cleared predicate device:

- Same Operating Principle
- Same Technology
- Same Intended Use

Design verification analysis was performed on the CrossTie™ Intraosseous Fixation System as a result of the risk analysis and product requirements. All analyses were verified to meet the required acceptance criteria. The subject device is the same as the predicate device (K141857),

with respect to materials, indications and technical characteristics. The only noted difference from the predicate device is the surgical technique allows the surgeon to use the suture for closure after joint reduction. This minor difference is insignificant in the safety and efficacy of the devices. In summary, the subject device described in this submission is substantially equivalent to the predicate device.

Indications for Use:

The indications for use are the same as the previously cleared indications for use for the CrossTie™ Intraosseous Fixation System: *The CrossTie™ Intraosseous Fixation System is indicated to aid in the fixation of fractures, fusions, and osteotomies of the toes, such as hammertoe, claw toe, mallet toe and inter-digital fusions.*

Device Description:

The CrossTie™ Intraosseous Fixation System is manufactured from implant grade PEEK. The implant is a one-piece construct designed to be press-fit into the intraosseous space of two adjoining bones to aid in fusion. The proximal and distal ends of the implant have barb-type features for securing the implant in position. The implant also features a hole in the distal end of the implant to be used at the surgeon's discretion to assist in joint reduction. Furthermore, the surgeon may optionally elect to use suture that passes through the distal end of the implant for closure.

The instruments needed for implantation consist of a reamer for implant site preparation and a driver for insertion. All associated instruments are Class I.

The design features of the CrossTie™ Intraosseous Fixation System are summarized below:

- Implant Grade PEEK
- Sized to accommodate patient anatomy
- Solid, one piece construction for all devices
- Proximal and distal barb-like features for secure placement
- Hole to optionally aid in joint reduction

Performance Testing:

The CrossTie™ Intraosseous Fixation System utilizes materials and has design features that are the same as the predicate device. Evaluation of the system with and without utilizing the suture for closure demonstrates that the subject device is substantially equivalent in static and fatigue performance compared to the predicate device. The implant has been cyclic tested with and without suture to demonstrate that the device can withstand the expected loads.