DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
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

May 3, 2016

Re: K160118
Trade/Device Name: STROPP™ (Single Tunnel Repair of Plantar Plate)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 14, 2016
Received: March 17, 2016

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

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)*

K160118

Device Name

STROPP(TM) System

Indications for Use *(Describe)*

The STROPP(TM) System is intended for use with a suture in metatarsal ligament and tendon repairs.

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:	April 27, 2016
Device Name:	Single Tunnel Repair of Plantar Plate (STROPP^{TM}) System
Company:	CrossRoads Extremity Systems 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:	Single Tunnel Repair of Plantar Plate (STROPP^{TM}) System
Common Name:	Suture Retention Device
Classification:	Class II
Regulation:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Panel:	87 - Orthopedic
Product Code:	MBI
Predicate Device:	**Primary Predicate** **K133229 Titanium Suture Anchor** MTP Solutions (Smith Nephew Hat Trick Lesser Toe Repair System) **Additional Predicate** **K133235 Threaded PEEK K-Wire** MTP Solutions (Smith Nephew Hat Trick Lesser Toe Repair System)

Device Description:

The STROPP^{TM} System is sterile packaged kit to include implants and instruments for plantar plate repair. Implants are 3.0 mm or 3.5 mm diameters and range in length from 6 mm to 12 mm. Implants are packaged with the following manual surgical

instruments for general use: a needle, needle passer, suture passer, an inserter, K-wires and distractor.

The implants are compatible with Size 0 suture; suture is not included with the system.

Indications for Use:

The STROPP™ System is intended for use with a suture in metatarsal ligament and tendon repairs.

Materials:

The STRoPP™ device is composed of polyetheretherketone (PEEK) per ASTM F2026.

Substantial Equivalence:

The subject STROPP™ System is substantially equivalent to the primary predicate device, K133229 (MTP Solutions Titanium Suture Anchor; Smith Nephew Hat Trick Lesser Toe Repair System) in intended use, surgical technique and principle of operation. The subject STROPP™ System is substantially equivalent to the additional predicate device, K133235 (MTP Solutions Threaded PEEK K-wire; Smith Nephew Hat Trick Lesser Toe Repair System) in its material of construction. The differences in technological characteristics between the predicates and the subject device do not raise any new or different questions of safety and effectiveness and is thereby substantially equivalent to the predicate devices.

The primary predicate device (K133229) contains threads for bone engagement that also interact with the suture. The subject device is a smooth press-fit device with no sharp edges or features to potentially impart damage to the suture. Both the subject and primary predicate (K133229) devices utilize a single bone tunnel technique and require the suture knot to be tied over the shoulder of the device. The primary predicate device (K133229) is manufactured from titanium alloy and the subject device is manufactured from PEEK (ASTM F2026), which is the same material as the additional predicate device (K133235). The primary predicate device (K133229) is available in one diameter (2.5mm) and the subject device is provided in two diameters (3.0mm and 3.5mm). The additional sizes of the subject device allow the surgeon to determine the optimal device size based on patient anatomy and bone quality. The primary predicate (K133229) is indicated for use with suture in the foot along with multiple expanded indications. While the indications for use of the subject device are encompassed in the indications for use of the primary predicate (K133229), they match exactly the indication for use of the additional predicate (K133235).

Performance Testing:

Non-clinical performance testing of the STROPP™ System has been performed to demonstrate substantial equivalence. Testing has been performed on test samples that are representative of the finished device. Non-clinical testing included

construct pull through testing in a simulated use model utilizing various suture materials to determine if the STRoPP™ construct could withstand the pull through forces that may be present in vivo. The construct pull through testing demonstrated statistical equivalence to current plantar plate repair options and that the STRoPP™ System introduces no additional failure modes. In addition, cadaveric simulated use testing was conducted to evaluate the interaction between the implant, bone and suture. The cadaveric testing resulted in no damage to the bone, implant or suture. All testing met the specified acceptance criteria and raised no new issues of safety or effectiveness. Based on the non-clinical test results, it can be concluded that the subject STRoPP™ System is substantially equivalent and is safe and effective for the intended use.