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

October 24, 2014

OthoDiscovery Group, LLC (D.B.A. CrossRoads Extremity Systems)
Mr. Vernon Hartdegen
Sr. Vice President of Operations
458 Distribution Parkway
Collierville, Tennessee 38017

Re: K142727
Trade/Device Name: CrossCLIP™ 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: JDR
Dated: September 25, 2014
Received: September 30, 2014

Dear Mr. Vernon 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,

Lori A. Wiggins -S

for
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)*
K142727

Device Name
CrossCLIP™ Implant System

Indications for Use *(Describe)*
The CrossCLIP™ Implant System is indicated for hand and foot bone fragment osteotomy fixation and joint arthrodesis.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5 – 510(k) Summary CrossCLIP™ Implant System

Date of Submission	September 25, 2014
Official Contact/Address of Manufacturing Facility	Vernon R Hartdegen Sr. Vice President of Operations OrthoDiscovery Group, LLC 458 Distribution Parkway Collierville, TN 38017 Phone: 901-221-8406 Fax: N/A vhartdegen@crextremity.com
Proprietary Name	CrossCLIP™ Implant System
Device Classification Name	Staple, Fixation, Bone
Product Code	JDR
Classification Reference	21 CFR 888.3030
Classification	Class II
Appropriate Classification Panel	87 - Orthopedic
Predicate Devices	K070031 – MemoMetal Memory Staples (MemoClip – EasyClip – For Fusion); MemoMetal Technologies K124045 – FuseForce Implant System; Solana Surgical, LLC
Reason For Submission	New Device

Substantial Equivalence:

The new device has the following similarities to the previously cleared predicate devices:

- Same Operating Principle
- Same Technology
- Same Intended Use

Design verification analysis was performed on the CrossCLIP™ Implant System as a result of the risk analysis and product requirements. Results of the design verification activities met the required acceptance criteria. In summary, the device described in this submission is substantially equivalent to the predicate device. The subject device is similar in material, operating principle and intended use to both identified predicates. The subject device primarily differs from the predicates in the manner of the attachment of the implant to the insertion

device/delivery instrument. The predicate devices both rely on insertion/delivery instrumentation and techniques that requires the delivery instrument to attach underneath the bridge of the staple. This prevents the staple from fully seating on the surface of the bone. Due to this, once the staple is released from its inserter and the legs are allowed to converge, the staple must then undergo a final seating with an ancillary instrument. The subject device implant is not held underneath the staple bridge rather the inserter engages the staple leg thereby allowing the implant to be fully seated on the bone prior to being released from the inserter/delivery instrument. Both the subject and predicate devices have barbs on the internal surface of the staple legs to resist pullout. In addition, certain sizes of the subject implant include a barb-like feature on the outside of the staple leg to resist pullout. Neither of these differences adversely affect the safety of the device as demonstrated by the verification analysis. The subject and predicate devices both utilize the same mechanism of action, i.e. the superelastic material property of nitinol, to generate compression between the staple legs. The minor differences between the subject and predicate devices are insignificant in the safety and efficacy of the devices. In summary, the subject device described in this submission is substantially equivalent to the predicate devices.

Indications for Use:

The CrossCLIP™ Implant System is indicated for hand and foot bone fragment osteotomy fixation and joint arthrodesis.

Device Description:

The CrossCLIP™ Implant System is manufactured from nickel titanium alloy (ASTM F2063-12 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants). The implants are one-piece devices designed to be implanted into the bones of the hand or foot for fragment osteotomy fixation and joint arthrodesis. The staple legs have barb-type features on the inside and outside of the legs to resist pullout. The implants are available in a range of sizes similar to the predicate devices.

The instruments needed for implantation consist of an implant inserter, drill/reamer guide, drill/reamer and provisional fixation pin. The implant inserter is considered a Class II instrument. All other instruments are Class I.

The design features of the CrossCLIP™ Implant System are summarized below:

- Implant Grade Nitinol (ASTM F2063-12)
- Various sizes to accommodate patient anatomy
- One piece construction
- Barbs to resist pull-out
- Single use, sterile packaged instruments

Performance Testing:

The CrossCLIP™ implants have been verified against the predicate device (K070031 – MemoMetal Memory Staples MemoClip – EasyClip – For Fusion; MemoMetal Technologies) and ASTM F2063-12 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants. The completed analysis has shown that the performance of the subject device is substantially equivalent to the predicate devices.