



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Nextremity Solutions, Incorporated
Mr. Ryan Schlotterback
Official Correspondent
54 Broad Street, Suite 200
Red Bank, New Jersey 07701

September 4, 2015

Re: K151160

Trade/Device Name: Arcus™ Staple 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: August 11, 2015

Received: August 12, 2015

Dear Mr. Schlotterback:

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" (21 CFR 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 Statement

510(k) Number: K151160

Device Name: Arcus™ Staple System

Indications For Use:

The Nextremity Solutions Arcus™ Staple System is indicated for fixation of bone fractures, bone reconstruction, ligament, soft tissue and tendon.

Examples include:

- Fixation of bone fragments or small bones fractures
- Fracture management in the foot and hand

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER
PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
(Per 21 CFR 807.92)

General Company Information:

Nextremity Solutions, Inc.
Ryan Schlotterback
210 North Buffalo Street
Warsaw, IN 46580

Date Prepared

August 11, 2015

General Device Information

Product Name:

Arcus™ Staple System

Classification:

Single/multiple component metallic
bone fixation appliances and
accessories
21 CFR 888.3030
Product code: JDR

Predicate Devices

Z-Medical, GmbH

Z-Medical, Z-Guide Staple System
(Marketed as Z-Staple)
[510(k) K121277]

Memometal Technologies

Varisation Staple
(Marketed as Varisation Staple)
[510(k) K070033]

Description

The Nextremity Solutions Arcus™ Staple System is a set, consisting of:

1. A bone staple.
2. Necessary surgical site sizing, preparation and insertion instruments (as a procedure pack).

The staples are fabricated from medical grade Titanium (ASTM F-136).

Intended Use (Indications)

The Nextremity Solutions Arcus™ Staple System is indicated for fixation of bone fractures, bone reconstruction, ligament, soft tissue and tendon.

Examples include:

- Fixation of bone fragments or small bones fractures
- Fracture management in the foot and hand

Substantial Equivalence

The Nextremity Solutions, Arcus™ Staple System possesses the same technological characteristics as the predicate devices. These characteristics include the intended use, basic design, material, size and fundamental technology.

Performance Data

Mechanical testing was performed as described in relevant recognized standards, including testing for 4 point bending (static and dynamic) and pull-out force for the Arcus™ Staple System as per ASTM F-564.