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

Nextremity Solutions, Incorporated
Mr. Ryan Schlotterback
Director, Product Development
210 North Buffalo Street
Warsaw, Indiana 46580

December 21, 2015

Re: K152548
Trade/Device Name: AXI+LINE™ Proximal Bunion Correction System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: November 20, 2015
Received: November 23, 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 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

Indications for Use Statement

510(k) Number (if known): K152548

Device Name: AXI+LINE™ Proximal Bunion Correction System

Indications for Use:

The AXI+LINE™ Proximal Bunion Correction System is indicated for fixation of fractures, osteotomies, non-unions and fusions of small bones and small bone segments in the foot and ankle.

Prescription Use ____X_____ **(Part 21 CFR 801 Subpart D)**	**AND/OR**	**Over-The-Counter Use __** **(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
(Prepared on September 1, 2015)

Pursuant to §513(i) (3) (A) of the Food, Drug, and Cosmetic Act, Nextremity Solutions, Inc. is submitting the following summary of information:

Trade Name: AXI+LINE™ Proximal Bunion Correction System

Sponsor:
Nextremity Solutions, Inc.
210 North Buffalo Street
Warsaw, IN 46580

Contact Person:
Ryan Schlotterback
Director, Product Development
210 North Buffalo Street
Warsaw, IN 46580
Direct: 574.485.2867
Mobile: 574.265.5308
Fax: 574.966.1396

Device Classification Name:
Single/multiple Component Metallic Bone Fixation Fastener Appliances and Accessories
21 CRF §888.3030
Product Code: HRS

Smooth or Threaded Metallic Bone Fixation Fastener and Accessories
21 CFR §888.3040
Product Code: HWC

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices:
K131061 – Nextremity Solutions – Restore™ Bunion Correction System
K140724 – Nextremity Solutions – MSP™ Metatarsal Shortening System
K143365 – Empirical Testing Corp.- Eminent Foot Plate System
K142581 – PaxMed International LLC – APTUS Foot System

The Nextremity Solutions AXI+LINE™ Proximal Bunion Correction System possesses the same technological characteristics as the predicate devices. These characteristics include the intended use, basic design, material, size and fundamental technology.

Device Description: The AXI+LINE™ Proximal Bunion Correction System is a plate system made from Titanium alloy. The geometry of the plate is that of a modified semi-tubular bone plate with a correction angle between the proximal and distal plate segments. The system also includes non-locking cortical and locking screws also made from Titanium alloy and necessary surgical site preparation and insertion instruments as a procedure pack.

Indications for Use: The Nextremity Solutions AXI+LINE™ Proximal Bunion Correction System is indicated for fixation of fractures, osteotomies, non-unions and fusions of small bones and small bone segments in the foot and ankle.

Safety and Performance: Finite Element Analysis was used to determine the worst-case plate configuration for the static and dynamic four-point bend testing.

Mechanical testing was performed as described in relevant recognized standards, including static and dynamic 4 point bend testing of the AXI+LINE™ Proximal Bunion Correction System plate per ASTM F-382 and axial push-out, insertion torque, and torque to failure testing of the locking and non-locking bone screws per ASTM F-543.

The product is made from the same material as the predicate Nextremity MSP Metatarsal Shortening System. The device components are comprised of standard medical Titanium alloy (ASTM F136) with a long history of successful use for the same and other orthopedic indications. Biocompatibility testing was, therefore, not performed in support of the proposed device.

Conclusion: Based on comparisons of the indications for use, technological characteristics, and the results of performance testing described above, the AXI+LINE™ Proximal Bunion Correction System has been shown to be substantially

equivalent to predicate devices used for the same clinical indications.