K131061

510(k) Summary
(Per 21 CFR 807.92)

General Company Information:

Nextremity Solutions, Inc.
Jorge A. Montoya
Director, Product Development
60 Broad Street, Suite 102
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AUG 2 8 2013

Date Prepared May 29, 2013

General Device Information

Product Name: Restore™ Fixation System

Classification: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3030
Product codes: JDR (staple fixation, bone) and HRS (plate fixation, bone)

Smooth or threaded metallic bone fixation fastener and accessories
21 CFR 888.3040
Product code: HWC (screw, fixation, bone)

Class II device

Predicate Devices

Z-Medical GmbH &Co. KG	Z-Guide Staple (Marketed as Z-Medical Staple) [510(k) K121277]
Arthrex Inc.	Arthrex Low Profile Screw (Marketed as Arthrex Low Profile Screw) [510(k) K103705]
Biomet Trauma	BioDrive™ Micro Screw System (Marketed as BioDrive™ Micro Nail Plate/Screw) [510(k) K092670]

Description

The Restore™ Fixation System consists of a compression staple and two non-locking cortical screws (one for optional use) with surgical site preparation and insertion instruments. The compression staple and cortical screw are fabricated from medical grade stainless steel alloy (ASTM F-139 and F-138) and are pre-packaged sterile.

Intended Use (Indications)

The Restore™ Fixation System is indicated for alignment, stabilization and fusion of fractures, osteotomies and arthrodesis of small bones such as the foot and ankle.

Substantial Equivalence

The Restore™ Fixation System possesses the same indication and technological characteristics (basic design, material, size and fundamental technology) of the predicate devices.

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 compression staple per ASTM F-564 and torque to failure and pull-out force for the non-locking cortical screw per ASTM F-543.

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

August 28, 2013

Mr. Jorge A. Montoya
Director, Product Development
Nextremity Solutions, Incorporated
60 Broad Street, Suite 102
Red Bank, New Jersey 07701

Re: K131061
Trade/Device Name: Restore™ Fixation 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, HRS, HWC
Dated: May 29, 2013
Received: May 30, 2013

Dear Mr. Montoya:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith

For

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): K131061

Device Name: Restore™ Fixation System

Indications For Use:

The Restore™ Fixation System is indicated for alignment, stabilization and fusion of fractures, osteotomies and arthrodesis of small bones such as the foot and ankle.

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)

Elizabeth L. Frank -S

Division of Orthopedic Devices