Nextremity Solutions, Inc.
Adam Finley
Assoc. Director, Product Development
210 North Buffalo Street
Warsaw, Indiana 46580

November 16, 2018

Re: K182201
Trade/Device Name: Stratum Foot Plating 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
Dated: October 20, 2018
Received: October 23, 2018

Dear Adam Finley:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2018.11.16 10:34:56 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182201

Device Name

Stratum™ Foot Plating System

Indications for Use *(Describe)*
The Nextremity Solutions Stratum™ Foot Plating System is a plate and screws construct indicated for fixation of fractures, osteotomies, non-unions, malunions and fusions of small bones and small bone segments, particularly in osteopenic bone.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"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."

510(k) Summary

Prepared: October 12, 2018

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

Contact: Adam Finley
Assoc. Director, Product Development
Adam.Finley@Nextremity.com
Phone: 574-807-6150

Proprietary Name: Stratum™ Foot Plating System

Common Name: Bone Plate System

Classifications: 21 CFR §888.3030: Single/Multiple Component Metallic Bone Fixation Fastener Appliances and Accessories; Class II

21 CFR §888.3040: Smooth or Threaded Metallic Bone Fixation Fastener; Class II

Product Codes: 87/HRS, 87/HWC

Substantially Equivalent Devices:

- Synthes, Inc. Modular Mini Fragment LCP System, K063049
- Nextremity Solutions MSP Metatarsal Shortening System, K140724
- Biomet A.L.P.S. Small Bone Locked Plating System, K131670

Device Description:

The Stratum™ Foot Plating System is a foot and ankle plating system consisting of plate and screw implants. The plates range in length from 26mm to 81.5mm and in width from 8.5mm to 29mm and feature between 2 and 10 screw holes. There are 6 different styles of screws; 2 diameters of non-locking screw, 3 diameters of fixed angle locking screws and 1 diameter of multi-directional locking screw. The screws range in length from 10mm to 70mm. Screws are available in sterile and non-sterile versions. The system also includes a sterile set of accessory instruments and individually packaged drill guides / drill bits designed for preparation of the implant site and insertion of devices into the bone. The plates, sterile screws, instrument kits, and drill guide / drill bits are all packaged individually in

separate sterile packaging. The non-sterile screws are provided in a case and tray suitable for steam sterilization. The plates, non-locking and locking screws are manufactured from Ti-6Al-4V ELI conforming to ASTM F136. The multi-directional locking screws are manufactured from Co-Cr-Mo conforming to ASTM F75.

Indications:

The Nextremity Solutions Stratum™ Foot Plating System is a plate and screws construct indicated for fixation of fractures, osteotomies, non-unions, malunions and fusions of small bones and small bone segments, particularly in osteopenic bone.

Summary of Technologies/Substantial Equivalence:

The Stratum Plate System is substantially equivalent to the predicate devices in regards to its intended use and indications, materials, designs, sizes, and mechanical properties. Differences between the subject device system and the predicate device systems do not raise different questions of safety and effectiveness.

Non-Clinical Testing:

To evaluate the strength of the Stratum™ Foot Plating System worst case plates were tested in static and dynamic four point bending with two different gap widths according to ASTM F382-99 and worst case screws were torqued to failure according to ASTM F543-13. These tests confirmed that the strength of the worst case Stratum plates and screws is substantially equivalent to predicate devices with similar indications and is adequate for their intended use. Bacterial Endotoxin Testing using the LAL method was performed and confirmed endotoxin levels of <20 EU/device.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Stratum™ Foot Plating System to the predicate devices.

Conclusions:

The Stratum™ Foot Plating System was demonstrated to be substantially equivalent to the predicate devices through having similar intended uses, similar technology characteristics and similar performance in side by side testing.