July 27, 2020

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

Re: K200785
Trade/Device Name: Stratum™ Reduced Size 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, HWC
Dated: March 24, 2020
Received: March 26, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K200785

Device Name
Stratum™ Reduced Size Foot Plating System

Indications for Use *(Describe)*

The Nextremity Solutions Stratum™ Reduced Size Foot Plating System is intended for stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the foot and ankle, 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.

510(k) Summary

Prepared: March 24, 2020

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

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

Proprietary Name: Stratum™ Reduced Size Foot Plating System

Common Name: Bone Plate System

Classifications: 21 CFR §888.3030 (Primary): 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 (Primary), 87 / HWC

Substantially Equivalent Devices:

- Zimmer Biomet F3™ Fragment Plating System (cleared as the DePuy Small Bone Locking Plating System), K081546 – Primary Predicate
- Zimmer Biomet A.L.P.S. Hand Fracture (cleared as the DePuy Small Bone Locking Plating System), K081546 – Primary Predicate
- Nextremity Solutions MSP Metatarsal Shortening System, K140724 – Additional Predicate
- Nextremity Solutions Stratum™ Foot Plating System, K182201 – Additional Predicate

Device Description:

The Stratum™ Reduced Size (RS) Foot Plating System is a foot and ankle plating system consisting of plate and screw implants. The plates range in length from 25.5mm to 59.53mm and in width from 6.35mm to 18mm and feature between 2 and 10 screw holes. There is one diameter, 2.4mm, for all screw types including locking, non-locking, and MDS screws. The screws range in length from 8mm to 50mm and are provided sterile. The system also includes a sterile set of accessory instruments along with individually packaged drill guides / drill bits, screw driver shafts, threaded wire with nut, and olive wires designed for preparation of the implant site and insertion of devices into the bone. The plates, screws, instrument kits, drill guide / drill bits, screw driver shafts, threaded wire with nut, and olive wires are all packaged individually in separate sterile packaging. 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 F1537.

Intended Use / Indications:

The Nextremity Solutions Stratum™ Reduced Size Foot Plating System is intended for stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the foot and ankle, particularly in osteopenic bone.

Summary of Technologies/Substantial Equivalence:

The Stratum™ Plate System Reduced Size 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 include plate profiles, geometries and screw hole configurations but do not raise new types of safety and effectiveness questions.

Non-Clinical Testing:

The worst case plate from the Stratum™ Reduced Size Foot Plating System was tested in static and analyzed in dynamic four point bending according to ASTM F382-14. Worst case screws were torqued to failure tested according to ASTM F543-13 and analyzed for insertion performance and pull-out strength. These analyses confirmed that the strength of the worst-case Stratum Reduced Size Foot Plating System plates and screws is substantially equivalent to predicate devices with similar indications and is adequate for their intended use. Bacterial Endotoxin Testing was performed using the LAL method, per AAMI ST72, USP 161 and USP 85, to confirm that endotoxin levels meet the requirement of < 20EU/device.

Clinical Testing:

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

Conclusion/Substantial Equivalence:

Differences between the subject device system and the predicate device systems do not raise new types of safety and effectiveness questions. The Stratum Reduced Size Foot Plating System is substantially equivalent to the predicate devices in regard to its intended use, material, design, sizes, and mechanical properties.