November 18, 2021

Nextremity Solutions, Inc.
Elise Fox
Quality and Regulatory Specialist
1195 Polk Drive
Warsaw, Indiana 46582

Re: K212640
Trade/Device Name: Stratum Ankle Fusion 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: August 19, 2021
Received: August 20, 2021

Dear Elise Fox:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212640

Device Name

Stratum® Ankle Fusion Plating System

Indications for Use *(Describe)*

The Stratum Ankle Fusion Plating System is indicated for use in stabilization and fixation of fractures or osteotomies, intra and extra articular fractures, and multi-fragmentary fractures, revision procedures, non-union and malunion, joint fusion and reconstruction of small bones of the feet and ankles including the distal tibia, talus, and calcaneus.

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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510(k) Summary

Prepared: November 18, 2021

Submitter: Nextremity Solutions, Inc.
1195 Polk Drive
Warsaw, IN 46582

Contact: Elise Fox
Quality and Regulatory Specialist
elise.fox@nextremity.com
Phone: 574-376-2062

Proprietary Name: Stratum® Ankle Fusion Plating System

Common Name: Plate, Fixation, Bone (Primary)
Screw, Fixation, Bone

Classification: II

Regulation Number: 21 CFR § 888.3030 (Primary) - Single/multiple component metallic bone fixation appliances and accessories

21 CFR § 888.3040 Smooth or threaded metallic bone fixation fastener

Panel: 87-Orthopedic

Product Code(s): HRS (Primary), HWC

Substantially Equivalent Devices:

- Paragon 28® Silverback™ Ankle Fusion Plating System(Cleared as Silverback Gorilla Plating System), K182148-Primary Predicate
- Zimmer Biomet Ankle Fix System 4.0(Cleared as Normed Medizin-Technik GmbH ANKLE FIX and ANKLE FIX PLUS Systems 4.0), K123347-Additional Predicate
- Nextremity Solutions Stratum Foot Plating System, K182201-Additional Predicate

Device Description:

The Stratum Ankle Fusion Plating System is a foot and ankle plating system consisting of plates and screw implants. The plates are 3.5mm thick, range in length from 73.66mm to 107.70mm, and range in width from 22.10mm to 40.64mm. The plates have between 10 and 13 locking screw holes and 1 to 2 slots. The plates are provided sterile. The system provides locking and non-locking screws that are available in diameters of 3.5mm and 5.0mm and range in length from 10mm to 80mm. The screws are provided sterile and non-sterile. The system includes cannulated

crossing screws that are 6.5mm in diameter and range from 26mm to 90mm in length. The cannulated screws are provided sterile. The plates and screws are manufactured from Ti-6Al-4V ELI conforming to ASTM F136.

The system is provided with a set of accessory instruments designed for preparation of the implant site and insertion of the implants into bone.

Intended Use / Indications:

The Stratum Ankle Fusion Plating System is indicated for use in stabilization and fixation of fractures or osteotomies, intra and extra articular fractures, and multi-fragmentary fractures, revision procedures, non-union and malunion, joint fusion and reconstruction of small bones of the feet and ankles including the distal tibia, talus, and calcaneus.

Summary of Technologies/Substantial Equivalence:

The Stratum Ankle Fusion Plating System is substantially equivalent to the predicate devices regarding the intended use and indications, material, design, sizes, and mechanical properties. The subject device and predicate devices share the same intended use of fusion and reconstruction of the small bones of the foot and ankle. The subject and predicate devices offer comparable anterior TT plates, lateral TT and TTC plates, posterior TTC plates, locking and non-locking screws, and cannulated crossing screws. Differences between the subject device system and the predicate device systems do not raise new types of safety and effectiveness questions.

Non-Clinical Testing:

For sterile product, endotoxin testing was performed using the Limulus Amebocyte Lysate (LAL) method according to AAMI ST72, USP 161 and USP 85. Results met the Endotoxin limit of $\leq$20 EU per device. To evaluate the strength of the Stratum Ankle Fusion Plating System and its components, axial pull-out strength and torque to failure tests were performed on worst case screws in accordance with ASTM F543-17. Static 4-point bend tests and dynamic 4-point bend tests were performed on the worst case implant construct according to ASTM F382. These tests confirmed that the strength of the Stratum Ankle Fusion Plating System is substantially equivalent to predicate devices with similar indications and is adequate for its intended use.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Stratum Ankle Fusion Plating System to the predicate device.

Conclusions/Substantial Equivalence:

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