December 21, 2021

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

Re: K213301
Trade/Device Name: InCore® Subtalar System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 30, 2021
Received: October 1, 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,

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)*

K213301

Device Name

InCore® Subtalar System

Indications for Use *(Describe)*

The Nextremity Solutions InCore® Subtalar System is intended for reduction and internal fixation of arthrodeses, osteotomies, and nonunions of the bones and joints of the foot. The three-part construct is specifically intended for internal fixation for Subtalar Joint Arthodesis (also known as Subtalar Joint Fusion).

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 - K213301

Prepared: September 30, 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
FAX: 574-966-1396

Proprietary Name: InCore® Subtalar System

Common Name: Bone Screw System

Classification: 21 CFR § 888.3040 Smooth or threaded metallic bone fixation fastener; Class II

Product Code: HWC

Substantially Equivalent Devices:

- Zimmer Biomet, TiMAX™ Cannulated Screw System (Cleared as Biomet Cannulated Screw System), K140891-Primary Predicate
- Nextremity Solutions, Stratum Foot Plating System, K182201-Additional Predicate

Device Description:

The InCore® Subtalar System consists of a post and two headless compression screws. Posts are available with an 8.0 mm diameter, in an 28mm length, and in right and left orientations. Screws are available in a 5.5 mm diameter and lengths of 50 to 120mm. The post is inserted into the talus and compression screws are inserted into the calcaneus and into the post to maintain apposition of the bones during fusion. A post plug screw is threaded into the top of the post after all components have been implanted to prevent tissue ingrowth into the post and facilitate removal, if needed. All implants are manufactured from color anodized Ti-6Al-4V alloy conforming to ASTM F-136.

The system is provided with a set of accessory instruments, including an implant specific targeting guide, designed for preparation of the implant site and insertion of the implants into bone.

Intended Use / Indications:

The Nextremity Solutions InCore® Subtalar System is intended for reduction and internal fixation of arthrodeses, osteotomies, and nonunions of the bones and joints of the foot. The three-part construct is specifically intended for internal fixation for Subtalar Joint Arthodesis (also known as Subtalar Joint Fusion).

Summary of Technologies/Substantial Equivalence:

The InCore® Subtalar System is substantially equivalent to the predicate devices regarding the intended use and indications, 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.

Non-Clinical Testing:

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 ≤20 EU per device. To evaluate the strength of the InCore® Subtalar System and components, torque to failure was performed on worst case compression screws and worst case constructs per ASTM F543. Static three-point bend and dynamic three-point bend tests were performed on worst case constructs per ASTM F382 and ASTM F1264. These tests confirmed that the strength of the InCore® Subtalar 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 InCore® Subtalar System to the predicate device.

Conclusions/Substantial Equivalence:

The InCore® Subtalar 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.