March 22, 2022

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

Re: K220181
Trade/Device Name: StealthFix Intraosseous 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, HWC
Dated: January 20, 2022
Received: January 21, 2022

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,

Limin Sun, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*
K220181

Device Name
StealthFix Intraosseous Fixation System

Indications for Use *(Describe)*
The StealthFix Intraosseous Fixation System is indicated for fixation of bone fractures, fusions, or for bone reconstructions, including:

- Arthrodesis in hand or foot surgery
- Mono or bi-cortical osteotomies in the foot or hand
- Fracture management in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment such as scarf, chevron, etc.

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.

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510(k) Summary

Prepared: March 22, 2022

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: StealthFix Intraosseous Fixation System

Common Name: Bone Staple System

Classification: 21 CFR § 888.3030 (Primary) Single/multiple component metallic bone fixation appliances and accessories; Class II

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

Product Code: JDR (Primary), HWC

Predicate Device: K163440- Stealth Staple System, First Ray LLC

Device Description:

The StealthFix Intraosseous Fixation System is an orthopedic intraosseous staple system consisting of staple and screw implants. The staples consist of two legs or posts connected by a bridge. The staples are available in post diameters of 2.5mm(mini), 3.5mm(small) and 4.5mm(standard). The 2.5mm staples are provided with a bridge span of 10mm and range in post length from 8mm to 12mm. The 3.5mm staples are provided with a bridge span of 15mm and range in post length from 14mm to 20mm. The 4.5mm staples are available in bridge spans of 15mm and 20mm and range in post length from 14mm to 32mm. The system provides crossing screws for optional fixation with the standard staple implants. Standard staples are designed with a screw slot to accept a crossing screw. The screws are 3.5mm in diameter with lengths ranging from 16mm to 38mm in 2mm increments. The system provides accessory instruments designed for preparation of the implant site and insertion of implants into bone, including implant specific inserters and targeting arms. The implants of the system are available packaged both sterile and non-sterile for single use. The instruments are provided non-sterile, reusable or non-sterile, single use and must

be cleaned and sterilized by the end user prior to use. The system also provides some instruments sterile packaged, individually and in sets.

Intended Use / Indications:

The StealthFix Intraosseous Fixation System is indicated for fixation of bone fractures, fusions, or for bone reconstructions, including:

- Arthrodesis in hand or foot surgery
- Mono or bi-cortical osteotomies in the foot or hand
- Fracture management in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment such as scarf, chevron, etc.

Summary of Technologies/Substantial Equivalence:

The StealthFix Intraosseous Fixation System is substantially equivalent to the predicate devices regarding the intended use and indications, material, design, sizes, and mechanical properties. The subject and predicates are both staple and screw implant systems manufactured from the same materials and are available in the same sizes. The subject system differs because the staple posts internal thread length was increased and because it contains non-cannulated screws.

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. An engineering analysis was performed to ensure that the modified staples do not create a new worst case for static and dynamic 4 point bend testing, and pullout force (ASTM F564). An engineering analysis was performed to ensure that the modified screws do not create a new worst case for torsional strength, pullout strength or insertion performance (ASTM F543).

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the StealthFix Intraosseous Fixation System to the predicate device.

Conclusions/Substantial Equivalence:

The StealthFix Intraosseous Fixation 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 different types of safety and effectiveness questions.