June 26, 2020

Nextremity Solutions, Inc.
Elise Fox
Quality Engineer
210 North Buffalo Street
Warsaw, Indiana 46580

Re: K200840
Trade/Device Name: DuoHex CH Cannulated Hammertoe System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, NDL
Dated: March 27, 2020
Received: March 31, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200840

Device Name
DuoHex™ CH Cannulated Hammertoe System

Indications for Use *(Describe)*
The Nextremity Solutions DuoHex™ CH Cannulated Hammertoe System is intended for small bone reconstruction limited to inter-phalangeal repair and fusion of the lesser toes.

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.

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510(k) Summary

Prepared: June 24th, 2020

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

Contact: Elise Fox
Quality and Regulatory Specialist
elise.fox@nextremity.com
Phone: 574-376-2062
FAX: 574-966-1396

Proprietary Name: DuoHex™ CH Cannulated Hammertoe System

Common Name: Bone Screw System

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

Product Code: HWC-primary product code, NDL

Substantially Equivalent Devices:

- Nextremity Solutions, Nextra Ti Hammertoe Correction System, K122031-Primary Predicate
- Nextremity Solutions, Nextra Hammertoe Correction System (Cleared as FlexFusion Fixation System), K110445- Additional Predicate
- Wright Medical Technology, Inc PHALINX Hammertoe System, K150252- Additional Predicate

Device Description:

The DuoHex™ CH Cannulated Hammertoe System consists of a two-part cannulated bone screw implant construct. The screw implants are provided in various sizes. The proximal screw implant diameters range from 2.75mm to 4.2mm. The middle screw implant diameters range from 2.75mm to 5.0mm in increments of 0.75mm. The proximal and distal screw implants are manufactured from Ti-6Al-4V ELI conforming to ASTM F136. The system offers an optional fixation method using a Kirschner wire (K-wire) in conjunction with the screw implants for additional fixation and temporary stabilization. The K-Wire is intended to be removed at the discretion of the physician upon joint fusion. The k-wires provided are manufactured from 316 Stainless Steel conforming to

ASTM F138. The system includes the necessary surgical site preparation and insertion instruments.

Intended Use / Indications:

The Nextremity Solutions DuoHex™ CH Cannulated Hammertoe System is intended for small bone reconstruction limited to inter-phalangeal repair and fusion of the lesser toes.

Summary of Technologies/Substantial Equivalence:

The DuoHex™ CH Cannulated Hammertoe 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 DuoHex™ CH Cannulated Hammertoe System and components, axial pull-out strength and torque to failure were performed on worst case screws according to ASTM F543-17. Static 3-point bend tests and dynamic 3-point bend tests were performed on the worst case implant construct according to ASTM F2193-18a. These tests confirmed that the strength of the DuoHex™ CH Cannulated Hammertoe 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 DuoHex™ CH Cannulated Hammertoe System to the predicate device.

Conclusions/Substantial Equivalence:

Differences between the subject device system and the predicate device systems do not raise new types of safety and effectiveness questions. The DuoHex™ CH Cannulated Hammertoe System is substantially equivalent to the predicate devices in regard to its intended use, material, design, sizes, and mechanical properties.