April 15, 2022

CrossRoads Extremity Systems, LLC
Kim Strohkirch
VP, QA/RA/Compliance
6423 Shelby View Drive, Suite 101
Memphis, Tennessee 38134

Re: K220797
Trade/Device Name: FootHold™ System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 17, 2022
Received: March 18, 2022

Dear Kim Strohkirch:

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

Laura C. Rose, Ph.D.
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)*
K220797

Device Name
FootHold System

Indications for Use *(Describe)*
FootHold™ System is intended to be used for suture or tissue fixation in the foot, ankle, hand, and wrist. Specific indications are listed below:

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP Joints for All Digits, Digital Tendon Transfers

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-Foot Reconstruction

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

Date:	April 14, 2022
Device Name:	*FootHold™System*
Establishment Registration:	3020584246
Company:	CrossRoads Extremity Systems 6423 Shelby View Dr., Suite 101 Memphis, TN 38134, USA *Recently acquired by DePuy Synthes, Inc, the orthopaedics company of Johnson & Johnson*
Contact Person:	Kim Strohkirch Vice President, QA/RA/Compliance CrossRoads Extremity Systems 901.221.8406 kstrohkirch@crextremity.com
Trade Name:	*FootHold™System*
Common Name:	Fastener, Fixation, Soft Tissue
Classification:	Class II
Regulation Number:	888.3040 Smooth or threaded metallic bone fixation fastener
Panel:	Orthopedic
Product Code:	MBI
Predicate Devices:	Primary Predicate: K153585 FlipButton Suture Anchor
Device Description:	The *FootHold™System* is a device which is preloaded with suture and is designed to attach soft tissues to bone. The device is deployed through a bicortical drill hole and secured on the far cortex.
Indications for Use:	*FootHold™System* is intended to be used for suture or tissue fixation in the foot, ankle, hand, and wrist. Specific indications are listed below:

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP Joints for All Digits, Digital Tendon Transfers

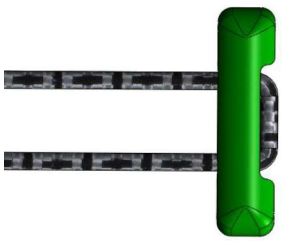
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-Foot Reconstruction

Materials: The *FootHold™System* implant components are manufactured from titanium alloy (ASTM F136).

Substantial Equivalence: Mechanical testing and analysis of the worst-case *FootHold™System* was performed to compare abrasion and construct pull-out strength for the subject and predicate devices. The results demonstrate the predicted performance of the *FootHold™System* is substantially equivalent to the predicate devices. There are no substantive differences between the *FootHold™System* and the cited predicates with respect to intended use and technological characteristics. The *FootHold™System* possesses the same technological characteristics as the predicate devices, including:

- Predicted performance and method of stabilization,
- Materials of manufacture,
- Basic design, and
- Mechanical properties.

Difference of suture strength and dimensions were evaluated, and the subject device is substantially equivalent to the predicate device.

	Subject Device	Predicate Device	Comparison
510(k)	N/A	K153585	Not applicable
Name	*FootHold™System*	Flip Button Suture Anchor	Not applicable
Images			Not applicable
Product Code	MBI (888.3040 Smooth or threaded metallic bone fixation fastener)	MBI (888.3040 Smooth or threaded metallic bone fixation fastener)	Identical
Indications for Use	*FootHold™System* is intended to be used for suture or tissue fixation in the foot, ankle, hand, and wrist. Specific indications are listed below:	The First Ray Flip Button Suture Anchor is intended to be used for suture or tissue fixation in the foot, ankle, hand, and wrist. Specific	Identical

	Subject Device	Predicate Device	Comparison
	Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP Joints for All Digits, Digital Tendon Transfers Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-Foot Reconstruction	indications are listed below: Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP Joints for All Digits, Digital Tendon Transfers Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-Foot Reconstruction	
Material	Medical grade titanium alloy (ASTM F136)	Medical grade titanium alloy (ASTM F136) PEEK (ASTM F2026)	Subset of material of predicate
Dimensions	Diameter: 1.1mm Length: 4.0mm Suture: #2-0 –Premium UHMWPE HS Fiber®, RB-0016VG (Riverpoint Medical, K190817) Blue-Blue	Diameter: 1.1mm, 2.0mm, 3.4mm Length: 4.0mm, 6.5mm, 10.0mm Suture: #2-0 - #2 Force Fiber Polyethylene Nonabsorbable Suture (TeleFlex, K063778)	Subset of predicate dimensions; Substantially equivalent suture
Sterilization	Sterile - Ethylene Oxide	Sterile - Ethylene Oxide	Identical

Performance Testing: Mechanical testing was conducted to demonstrate the suture does not present a new worst-case for abrasion strength. Bench testing for mechanical pull-out strength shows that there was a statistically significant improvement of pull-out strength for the subject device as compared to the listed predicate.

A sterility assurance level (SAL) of 10^{-6} has been established in conformance with ANSI/AAMI/ISO 11135-1. The validation meets the residuals of ethylene oxide and ethylene chlorohydrin are below the thresholds specified in ANSI/AAMI/ISO 10993-7. Packaging has met all acceptance criteria for labeling of 5-year shelf life (ISO ISO11607-2). Bacterial endotoxin testing meets the established limits.

Based on the comparative analysis, subject *FootHold™System* meets ISO 10993-1 for biocompatibility. The results demonstrate the performance of the subject *FootHold™System* is substantially equivalent to the predicate device.

Conclusion:

There are no substantial differences between the *FootHold™System* and the predicate devices with respect to intended use and technological characteristics, including basic design, materials of manufacture, mechanical properties, and intended effect.

Therefore, the *FootHold™System* can be found substantially equivalent to the cited predicate, as it does not raise new questions of safety and effectiveness.