November 16, 2021

Wright Medical Technology, Inc.
Michael Mullins
Staff Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 37117

Re: K212996
Trade/Device Name: Sterile PHALINX Hammertoe System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTY
Dated: September 17, 2021
Received: September 20, 2021

Dear Michael Mullins:

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, M.P.H.
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)*
K212996

Device Name
Sterile PHALINX Hammertoe System

Indications for Use *(Describe)*
The PHALINX™ Hammertoe System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated Implants in the PHALINX™ Hammertoe Fixation System can be used with k-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Sterile PHALINX® Hammertoe System.

Submitted by:
Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Contact Person:
Michael Mullins
Staff Regulatory Affairs Specialist
Phone: 901-867-4142
Fax: 901-867-4190

Date Prepared: 16-November-2021

Proprietary Name: Sterile PHALINX Hammertoe System

Primary Product Code–Device Panel: HWC – Orthopedic
Primary Common Name: Screw, Fixation, Bone

Secondary Product Code–Device Panel: HTY – Orthopedic
Secondary Common Name: Pin, Fixation, Smooth

Classification Name: Smooth or threaded metallic bone fixation fastener

Regulation Number: 21 CFR 888.3040 – Class II

Device Class: Class II

Primary Predicate: K150252: PHALINX Hammertoe

Additional Predicates: N/A

Reference Device: K203832: FUSEFORCE™ Flex Dynamic Compression System
K140148: PROTOE Hammertoe Fixation System

Description
This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market a gamma sterilized version of the PHALINX Hammertoe system. The subject PHALINX® Hammertoe System implants are designed to facilitate fixation of osteotomies and reconstruction of the lesser toes. The implants have barbed proximal and interrupted distal threads fixation features and are offered in multiple sizes. The subject PHALINX hammertoe implant is single piece titanium device offered in straight cannulated and angled 10° solid options and remains identical to the predicate in design. The subject cannulated hammertoe implants can be implanted temporarily with k-wires (0.9, 1.1, 1.4 mm) to stabilize outlying joints. These k-wires were originally cleared under K142585 and a minor modification to the length of the k-wire is being made in this submission.

Indications for Use

The PHALINX® Hammertoe System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated Implants in the PHALINX® Hammertoe System can be used with k-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

Technological Characteristics Comparison

The subject PHALINX hammertoe implants are identical to the predicate in implant design, material, and intended use. Further, the subject k-wires are identical to the predicate k-wires except for being longer. Lastly, the predicate system is offered nonsterile while the subject system is offered gamma sterilized.

Non-Clinical Testing

- Pyrogenicity testing was conducted using the bacterial endotoxins test on the subject device per ANSI/AAMI ST 72.
- Engineering analysis was provided to evaluate MR compatibility of the subject device per ASTM F2182 (RF Heating), ASTM F2062 ()/ASTM F2213 (Induced Force /Induced Torque), and ASTM F2119 (Image Artifact).

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject has the same Indications for Use as the predicate device, and equivalent technological characteristics to the predicate device. Therefore, the information provided in this submission demonstrates substantial equivalence of the subject device to the predicate device.