December 16, 2022

Paragon 28, Inc.
Haylie Hertz
Senior Regulatory Affairs Specialist
14445 Grasslands Dr.
Englewood, Colorado 80112

Re: K223184
Trade/Device Name: Phantom Metatarsal Shortening 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: October 21, 2022
Received: October 24, 2022

Dear Haylie Hertz:

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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K223184

Device Name
Phantom Metatarsal Shortening System

Indications for Use *(Describe)*
The Phantom Metatarsal Shortening System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device. Specific examples include:

Metatarsal and phalangeal osteotomies
Metatarsal deformity correction
Hammertoe
Revision hammertoe
Claw toe
Mallet toe
Proximal Interphalangeal Joint Arthrodesis
Distal Interphalangeal Joint Arthrodesis

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

510(k) Number:	K223184
Manufacturer:	Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112
Contact:	Haylie Hertz Senior Regulatory Affairs Specialist Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112 Phone: 303-720-0017 hhertz@paragon28.com
Date Prepared:	December 15, 2022
Device Trade Name:	Phantom Metatarsal Shortening System
Device Class and Common Name:	Class II, Screw, Fixation, Bone
Classification:	21 CFR 888.3040: Single/multiple component metallic bone fixation appliances and accessories.
Product Codes:	HWC, HTY
Indications for Use:	The Phantom Metatarsal Shortening System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device. Specific examples include: • Metatarsal and phalangeal osteotomies • Metatarsal deformity correction • Hammertoe • Revision hammertoe • Claw toe • Mallet toe

- Proximal Interphalangeal Joint Arthrodesis
- Distal Interphalangeal Joint Arthrodesis

Device Description: The Phantom Metatarsal Shortening System includes a series of titanium (Ti-6Al-4V ELI per ASTM F136) intramedullary implants used for the correction of small bones in the foot. The implants are designed to provide stability and fixation of bone fragments to ultimately achieve fusion.

Primary Predicate Device: Monster Screw System (K203011)

Additional Predicate: HammerTube System (K171715)

Reference Devices: ITS HOL Plate (K131722)
Phantom Small Bone Intramedullary Nail System (K182307)

Substantial Equivalence: The Phantom Metatarsal Shortening System is substantially equivalent to the legally marketed predicate devices with respect to intended use and design.

Performance Testing: All necessary testing has been performed on representative Phantom Metatarsal Shortening System components to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended. All testing was performed on finished devices.
The device performance was characterized via torque to failure per ASTM F543, insertion and removal torque per ASTM F543, static pullout of threads per ASTM F543, static pullout of the prongs, static cantilever bending, and dynamic cantilever bending testing.
Clinical data are not needed to support the safety and effectiveness of the subject device.

Conclusions: The Phantom Metatarsal Shortening System subject to this submission possess the same intended use and technological characteristics as the predicate devices. All performance testing conducted for the Phantom Metatarsal Shortening System met the predetermined acceptance criteria. As such, the Phantom Metatarsal Shortening System is substantially equivalent to the predicate devices for the intended use.