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

June 28, 2021

Re: K210869
Trade/Device Name: Phantom® Hindfoot TTC/TC Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: May 28, 2021
Received: June 2, 2021

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,

Michael Owens
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210869

Device Name
Phantom® Hindfoot TTC/TC Nail System

Indications for Use *(Describe)*

The Phantom® Hindfoot TTC/TC Nail system is intended for tibiotalocalcaneal arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot.
Examples of specific indications include:

- Post-traumatic or degenerative arthritis
- Previously infected arthrosis
- Revision of failed ankle arthrodesis
- Revision of failed total ankle arthroplasty
- Talar deficiency conditions such as avascular necrosis of the talus (requiring tibiocalcaneal arthrodesis)
- Neuromuscular deformity or other neuromuscular disease with severe deformity or instability of the ankle
- Rheumatoid arthritis
- Osteoarthritis
- Nonunions or pseudarthrosis of hindfoot and distal tibia
- Trauma (severe or malunited tibial pilon fracture)
- Charcot foot (neuroarthropathy)
- Severe end-stage degenerative arthritis
- Instability and skeletal defects after tumor resection
- Pantalar arthrodesis
- Severe foot/ankle deformity

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

510(k) Number: K210869

Device Trade Name: Phantom® Hindfoot TTC/TC Nail System

Manufacturer:
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112

Contact:
Ms. Haylie Hertz
Regulatory Affairs Specialist
Phone: 303.720.0017
hhertz@paragon28.com

Date Prepared: May 28, 2021

Classification:
21 CFR §888.3020, Intramedullary Nail, Bone Screw
21 CFR §888.3040, Screw, fixation, bone

Class: II

Product Code: HSB, HWC

Common Name: Intramedullary Nail

Predicate Device: Phantom® Hindfoot TTC/TC Nail System (K201227)

Reference Device: Anatomic Ankle Arthrodesis Interlocking Nail (K130147)

Indications for Use: The Phantom® Hindfoot TTC/TC Nail System is intended for tibiotalocalcaneal arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot. Examples of specific indications include:

- Post-traumatic or degenerative arthritis
- Previously infected arthrosis
- Revision of failed ankle arthrodesis
- Revision of failed total ankle arthroplasty
- Talar deficiency conditions such as avascular necrosis of the talus (requiring tibiocalcaneal arthrodesis)
- Neuromuscular deformity or other neuromuscular disease with severe deformity or instability of the ankle
- Rheumatoid arthritis

- Osteoarthritis
- Nonunions or pseudarthrosis of hindfoot and distal tibia
- Trauma (severe or malunited tibial pilon fracture)
- Charcot foot (neuroarthropathy)
- Severe end-stage degenerative arthritis
- Instability and skeletal defects after tumor resection
- Pantalar arthrodesis
- Severe foot/ankle deformity

Device Description: The Paragon 28® Phantom® Hindfoot TTC/TC Nail System is comprised of intramedullary nails, screws and accessory components. The Phantom® nails are offered in a variety of sizes lengths, and configurations to accommodate variations in patient anatomy. The Phantom® screws insert through the intramedullary nail to secure the construct. These are offered in varying lengths to accommodate the anatomical fixation required.

Substantial Equivalence:
The intended use of the subject device is the same as the predicate device. In addition, the subject device possesses the same technological characteristics as the predicate device, including performance, basic design, material, manufacturing, and sizes. Differences between the Phantom® nails and the predicate device (i.e. nail shape and screw diameter) were shown not to raise new questions of safety and effectiveness. Therefore, the Phantom® Hindfoot TTC/TC Nail System is substantially equivalent to the predicate device with respect to indications, design, function, and performance.

Preclinical Testing:
Static and dynamic mechanical testing per ASTM F1264 was conducted on the Phantom® Hindfoot Curved Nail. A cadaveric implantation study was also conducted. Biocompatibility was evaluated per ISO 10993-1 and CDRH's 2020 Biocompatibility Guidance Document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".* Additional testing includes bacterial endotoxins and sterilization.

Conclusion:
The Phantom® Hindfoot Curved Nail has the same intended use and equivalent technological characteristics as the predicate devices. Additionally, the preclinical testing supports the substantial equivalence of the Phantom® Hindfoot Curved Nail to the predicate. Therefore, the Phantom® Hindfoot TTC/TC Nail System is substantially equivalent for its intended use.