March 5, 2026

Paragon 28, Inc.
Brittanie Dogue
Regulatory Affairs Specialist II
14445 Grasslands Dr.
Englewood, Colorado 80112

Re: K253591
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: January 30, 2026
Received: February 2, 2026

Dear Brittanie Dogue:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FARZANA SHARMIN -S

Farzana Sharmin, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253591

Please provide the device trade name(s).

Phantom® Hindfoot TTC/TC Nail System

Please provide your Indications for Use below.

The Phantom® Hindfoot TTC/TC Nail System is indicated 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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Manufacturer: Paragon 28, Inc.
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Englewood, CO 80112

Contact: Brittanie Dogué
Regulatory Affairs Specialist II
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
Phone: 720-808-7119
Brittanie.dogue@zimmerbiomet.com

Date Prepared: March 04, 2026

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

Device Class: Class II

Primary Predicate(s): Phantom® Hindfoot TTC/TC Nail System (K251850)

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

Classification and Product Codes:

21 CFR 888.3020; Rod, Fixation, Intramedullary And Accessories	HSB
21 CFR 888.3040; Screw, Fixation, Bone	HWC

Indications for Use:

The Phantom® Hindfoot TTC/TC Nail System is indicated 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:

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

Substantial Equivalence:

The purpose of this Traditional 510(k) is to obtain clearance of Magnetic Resonance (MR) safety and compatibility testing and Magnetic Resonance Imaging (MRI) Safety Information updates to the labeling of the previously cleared and legally marketed Paragon 28 Phantom® Hindfoot TTC Trauma Nails. There are no other indications for use, design, material, processing, performance, or labeling modifications subject to the submission.

The intended use, principle of operation and fundamental scientific technology of the modified device are identical to the predicate device. The MR safety and compatibility performance and labeling modifications were accomplished via testing in the MRI environment and updated labeling per the FDA Guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment” issued October 10, 2023. The data demonstrate substantial equivalence and the subject modifications do not raise new issues of safety or effectiveness.

Performance Testing:

MR Safety and Compatibility Testing has been completed and presented in the submission as recommended in the FDA Guidance “Testing and Labeling Medical Devices for Safety in the Magnetic

Resonance (MR) Environment" issued October 10, 2023, including FDA-recognized standards tests for the following potential hazards:
• Image Artifact per ASTM F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants
• Magnetically Induced Displacement Force per ASTM F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
• Magnetically Induced Torque per ASTM F2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
• Radiofrequency (RF) Induced Heating per ASTM F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance Imaging

Based on the results, each device will be labeled as "MR Conditional" with MRI Safety Information in the instructions for use as described in ASTM F2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.*

Conclusions: The subject device possesses identical indications for use, technological characteristics, and principles of operation as the predicate. The proposed device modification (MR Conditional patient safety information) does not raise new issues of safety or effectiveness and has been fully evaluated per the FDA Guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" issued October 10, 2023. The subject device is substantially equivalent to the legally marketed, predicate Paragon 28 Phantom® Hindfoot TTC Trauma Nails.