January 14, 2019

Paragon 28, Inc.
Mr. Eric Lintula
Director of Regulatory Affairs
4B Inverness Ct. E., Ste 280
Englewood, Colorado 80112

Re: K182307
Trade/Device Name: Small Bone Phantom® Intramedullary Nail System; TTC Phantom® Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB, KTW, HWC
Dated: December 20, 2018
Received: December 31, 2018

Dear Mr. Lintula:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2019.01.14 13:28:37 -05'00'

FOR Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K182307

Device Name
Small Bone Phantom® Intramedullary Nail System

Indications for Use *(Describe)*
The Small Bone Phantom® Intramedullary Nail System is indicated for use in stabilization and fixation of the small bones of the feet and ankle for the treatment of fractures, osteotomies, nonunions, pseudarthroses and malunions by revision, joint fusion or reconstruction procedures.

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
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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)*

K182307

Device Name

TTC Phantom® Intramedullary Nail System

Indications for Use *(Describe)*

The TTC Phantom® Intramedullary 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

Date:	October 3rd, 2018
Sponsor: **Sponsor contact:**	Paragon 28, Inc. 4B Inverness Ct. E., STE 280 Englewood, Colorado 80112 Phone: (888) 728-1888 Fax: (888) 728-1220 Eric Lintula, Director of Regulatory Affairs
Trade Names:	Small Bone Phantom® Intramedullary Nail System TTC Phantom® Intramedullary Nail System
Small Bone Phantom® Regulatory Class:	Class II
TTC Phantom® Regulatory Class:	Class II
Small Bone Phantom® Regulation, Product Code, Classification, and Common Name:	888.3030, KTW, Appliance, fixation, nail/blade/plate combination, single component 888.3040, HWC, Smooth or threaded metallic bone fixation fastener, bone screw
TTC Phantom® Regulation, Product Code, Classification, and Common Name:	888.3020, HSB, Rod, Fixation, Intramedullary And Accessories 888.3040, HWC, Smooth or threaded metallic bone fixation fastener, bone screw
Small Bone Phantom® Device Description:	The Paragon 28® Small Bone Phantom® Intramedullary Nail System is comprised of small bone intramedullary nails, locking screws and threaded pegs. The Small Bone Phantom® nails are offered in a variety of lengths to accommodate variations in patient anatomy. The Small Bone Phantom® threaded pegs and locking screws insert through the intramedullary nail to secure the construct. These are offered in varying lengths to accommodate the anatomical fixation required. The system includes instruments for implantation.
TTC Phantom® Device Description:	The Paragon 28® TTC Phantom® Intramedullary Nail System is comprised of intramedullary nails, screws and accessory components. The TTC Phantom® nails are offered in a variety of sizes and lengths to accommodate variations in patient anatomy. The TTC Phantom® screws insert through the intramedullary nail to secure the construct. These are offered in varying lengths to accommodate the anatomical fixation required.

Small Bone Phantom® Materials:	The Small Bone Phantom® Intramedullary Nail System implants are made from Titanium Alloy (ASTM F136). The instrumentation is manufactured from medical grades of titanium alloy, stainless steel, anodized aluminum and polymer.
TTC Phantom® Materials:	The TTC Phantom® Intramedullary Nail System implants are made from Titanium Alloy (ASTM F136). The instrumentation is manufactured from medical grades of titanium alloy, stainless steel, anodized aluminum and polymer.
Small Bone Phantom® Indications for Use:	The Small Bone Phantom® Intramedullary Nail System is indicated for use in stabilization and fixation of the small bones of the feet and ankle for the treatment of fractures, osteotomies, nonunions, pseudarthroses and malunions by revision, joint fusion or reconstruction procedures.
TTC Phantom® Indications for Use:	The TTC Phantom® Intramedullary 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
Small Bone Phantom® Primary Predicate:	K170693, Phantom™ Small Bone Intramedullary Nail System
TTC Phantom® Primary Predicate:	K171376, DynaNail™ Ankle Arthrodesis Nail

TTC Phantom® Additional Predicates:	K120419, Dyna Locking Ankle Nail™ K123810, Piccolo Composite® Nailing System – Ankle Arthrodesis K130147, SBi Anatomic Ankle Arthrodesis Interlocking Nail System
Small Bone Phantom® Comparison to Predicate Indications:	The subject Small Bone Phantom® Intramedullary Nail System is a modification of the unmodified Phantom™ Small Bone Intramedullary Nail System, and therefore has the same indications.
TTC Phantom® Comparison to Predicate Indications:	The subject TTC Phantom® Intramedullary Nail System and predicate DynaNail™ Ankle Arthrodesis Nail, Dyna Locking Ankle Nail™, Piccolo Composite® Nailing System for Ankle Arthrodesis, and SBi Anatomic Ankle Arthrodesis Interlocking Nail System devices are intended to be used for tibiotalocalcaneal arthrodesis. All devices are indicated for use in the hindfoot and ankle. All indications for the subject device are within the indications of the predicate devices.
Small Bone Phantom® Comparison to Predicate Technological Characteristics:	The subject Small Bone Phantom® intramedullary nail and components possess the same technological characteristics as the predicate device. These include: • performance, • basic design, • material, manufacturing and • sizes (dimensions are comparable to those offered by the predicate systems). Therefore, the fundamental scientific technology of the subject Small Bone Phantom® intramedullary nail and components is similar to the previously cleared device.
TTC Phantom® Comparison to Predicate Technological Characteristics:	The subject TTC Phantom® intramedullary nail and components possess the same technological characteristics as the predicate devices. These include: • performance, • basic design, • material, manufacturing and • sizes (dimensions are comparable to those offered by the predicate systems). Therefore, the fundamental scientific technology of the subject TTC Phantom® intramedullary nail and components is similar to previously cleared devices.
Small Bone Phantom® Performance Data:	Engineering analysis is presented to provide evidence that the subsequent performance of the Small Bone Phantom® Intramedullary Nail System is not adversely affected by the design modifications. The results of the analysis demonstrated the subject devices are substantially equivalent to the Phantom™ Small Bone Intramedullary Nail predicate.

TTC Phantom® Performance Data:	All necessary testing has been performed on representative TTC Phantom® Intramedullary Nail System components. The device performance was characterized via four-point bend testing per ASTM F1264. Clinical data are not needed to support the safety and effectiveness of the subject devices. Engineering analysis is presented to assure substantial equivalence of the TTC Phantom® Intramedullary Nail System to its predicates. The results of the analysis demonstrated the subject devices are substantially equivalent to the Dyna Locking Ankle Nail™ and Piccolo Composite® Nailing System predicates.
Conclusion:	Engineering analysis demonstrates the substantial equivalence of the Small Bone Phantom® Intramedullary Nail System to the Phantom™ Small Bone Intramedullary System and the TTC Phantom® Intramedullary Nail System to the Dyna Locking Ankle Nail™ and Piccolo Composite® Nailing System. Therefore, the Phantom® Intramedullary Nail Systems are substantially equivalent to the predicate devices with respect to their indications for use, technical characteristics, and function.