DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 19, 2017

Paragon 28, Inc.
% Karen Warden
Representative/Consultant
BackRoads Consulting, Inc
PO Box 566
Chesterland, Ohio 44026-0566

Re: K170693
Trade/Device Name: Phantom Small Bone Intramedullary Nail System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTW, HWC
Dated: March 6, 2017
Received: March 7, 2017

Dear Karen Warden:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K170693

Device Name

Phantom™ Small Bone Intramedullary Nail System

Indications for Use *(Describe)*

The Phantom™ Small Bone 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date:	6 March 2017
Sponsor:	Paragon 28, Inc. 4B Inverness Ct. E., STE 280 Englewood, Colorado 80112 Phone: (888) 728-1888, Facsimile: (888) 728-1220
Sponsor Contact:	Frank S. Bono, Chief Technology Officer
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Names:	Phantom™ Small Bone Intramedullary Nail System
Common Name:	Combination nail/plate
Regulatory Class:	Class II
Classification Name, Regulation, Product Code:	Appliance, fixation, nail/blade/plate combination, single component, 888.3030, KTW Screw, Fixation, Bone, 888.3040, HWC
Device Description:	The Phantom™ Small Bone Intramedullary Nail System is comprised of small bone intramedullary nails, locking screws and threaded pegs. The Phantom™ nails are offered in a variety of lengths to accommodate variations in patient anatomy. The 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.
Indications for Use:	The Phantom™ Small Bone 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.
Materials:	The Phantom™ Small Bone Intramedullary Nail System implants are manufactured from medical grade titanium alloy (per ASTM F136).
Primary Predicate:	ParaLock Plating System™ (Paragon 28, Inc. – K140397)
Performance Data:	Mechanical testing of the worst case Phantom™ nail included static and dynamic bending performed according to ASTM F382. Mechanical testing of the worst case Phantom™ locking screw and threaded peg included torsion, insertion/removal and pullout performed according to ASTM F543. The mechanical test results and predicate comparisons demonstrated that the mechanical performance of the Small Bone Intramedullary Nail System is substantially equivalent to the predicate.
Technological Characteristics:	The Phantom™ Small Bone Intramedullary Nail System possesses similar technological characteristics compared to the predicate device. These include: • performance, • basic design, • material, manufacturing and • sizes (dimensions are comparable to those offered by the predicate systems). The difference in the stabilization method between the subject and predicate devices, i.e., combination nail/plate versus plate, did not raise

	new questions of safety or effectiveness. Therefore the fundamental scientific technology of the Phantom™ Small Bone Intramedullary Nail System is substantially equivalent to previously cleared devices.
Conclusion:	The Phantom™ Small Bone Intramedullary Nail System possesses indications for use and technological characteristics the same as and similar to the predicate devices. Therefore the Phantom™ Small Bone Intramedullary Nail System is substantially equivalent to the predicates.