Paragon 28, Inc.
Haylie Fast
Associate Manager of Regulatory Affairs
14445 Grasslands Drive
Englewood, Colorado 80112

August 22, 2024

Re: K234128
Trade/Device Name: Phantom Fibula Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 24, 2024
Received: July 24, 2024

Dear Haylie Fast:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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.

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
Digitally signed by Farzana Sharmin -S
Date: 2024.08.22 14:59:46 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234128

Device Name

Phantom Fibula Nail System

Indications for Use *(Describe)*

The Phantom Fibula Nail System is intended for use in the fixation of fibular fractures and osteotomies.

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

Manufacturer:	Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112
Contact:	Haylie Fast Associate Manager of Regulatory Affairs Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112 Phone: 720-994-5489 hfast@paragon28.com
Date Prepared:	August 21, 2024
Device Trade Name:	Phantom Fibula Nail System
Device Class and Common Name:	Class II, Rod, Fixation, Intramedullary and Accessories
Classification:	21 CFR 888.3020: Intramedullary Fixation Rod
Product Codes:	HSB, HWC
Indications for Use:	The Phantom Fibula Nail System is intended for use in the fixation of fibular fractures and osteotomies.
Device Description:	The Phantom Fibula Nail System consists of nails, screws, and accessories for the intended use of fibula repair. The implants are provided in multiple sizes and lengths.
Primary Predicate:	AOS Small Bone Nailing System (K163014)
Additional Predicate:	Arthrex FibuLock Nail (K173656)
Reference Device:	Acumed Small Bone IM Nail System (K143276)

Substantial Equivalence:	The Phantom Fibula Nail System is substantially equivalent to the legally marketed predicate device system with respect to intended use and design. The technological characteristics between the subject device, primary predicate and reference devices are similar. For the primary predicate and subject device, both nails are angled, and both devices allow the use of syndesmotic repair devices in place of a syndesmotic screw. The lengths of the subject device nails are within the range of the primary predicate and reference devices. The subject device contains screws with diameters and lengths that are included in either the primary predicate or reference devices. The subject device and additional predicate device each contain a proximal fixation feature. The differences in technological characteristics between the subject device, predicate device and reference devices were shown not to introduce new questions of safety and effectiveness.
Performance Testing:	All necessary testing has been performed on representative Phantom Fibula Nail 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 Phantom Fibula Nail has been tested in accordance with ASTM F1264, the screws have been tested in accordance with ASTM F543, and the device was tested for corrosion potential in accordance with ASTM F1875. Clinical data are not needed to support the safety and effectiveness of the subject device.
Conclusions:	Based on the same intended use, similar technological characteristics, and supportive performance testing, the Phantom Fibula Nail System was found to be substantially equivalent to the predicate device.