September 30, 2025

Paragon 28, Inc.
Edward Wells-Spicer
Regulatory Affairs Specialist II
14445 Grasslands Drive
Englewood, Colorado 80112

Re: K252106
Trade/Device Name: External Fixation Mini Rail System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT
Dated: August 29, 2025
Received: August 29, 2025

Dear Edward Wells-Spicer:

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.

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,

Lixin Liu -S

Lixin Liu, Ph.D
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.	K252106/S001

Please provide the device trade name(s).

External Fixation Mini Rail System

Please provide your Indications for Use below.

The External Fixation Mini Rail System is intended for external fixation and is indicated for stabilization of fractures and osteotomy, foot arthrodesis, adult and pediatric leg lengthening, and correction of bone deformity in the lower extremities. The External Fixation Mini Rail System is intended to be used in pediatric patients that are children aged 2 years to less than 12 years and adolescents aged 12 through 21 years (up to but not including the 22nd birthday).

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

Device Trade Name: External Fixation Mini Rail System

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

Contact:
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Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
Edward.wellsspicer@zimmerbiomet.com

Date Prepared: September 29, 2025

Common or Usual Name: External Fixation System

Classifications: 21 CFR §888.3030; Single/multiple component metallic bone fixation appliances and accessories.

Class: II

Product Codes: KTT; appliance, fixation, nail/blade/plate combination, multiple component

Indications for Use:
The External Fixation Mini Rail System is intended for external fixation and is indicated for stabilization of fractures and osteotomy, foot arthrodesis, adult and pediatric leg lengthening, and correction of bone deformity in the lower extremities. The External Fixation Mini Rail System is intended to be used in pediatric patients that are children aged 2 years to less than 12 years and adolescents aged 12 through 21 (up to but not including the 22nd birthday).

Device Description:
The External Fixation Mini Rail System consists of pins, rail, wires and pins clamps. The mini rail frame serves as the structural base for fixation distraction. The pin clamps allow rotational and translational positioning of bone segments. The system is meant to offer a solution for compression and gradual distraction of the metatarsals and 1st metatarsophalangeal (MTP) joint. The system also includes instrumentation for implantation such as wires, drivers, sawblades, wrenches, templates and cut guides.

Primary Predicate Device:

Table 1: Primary Predicate Device

Device Name(s)	Manufacturer	K-Number
Dynex Micro	Vilex, LLC	K202143

Secondary Predicate Device:

Table 1: Secondary Predicate Device

Device Name(s)	Manufacturer	K-Number
Arrowhead Mini-Rail Fixator	Arrowhead DE, LLC	K162032

Reference Device:

Table 2: Reference Device

Device Name(s)	Manufacturer	K-Number
Monkey Rings External Fixation System	Paragon 28, Inc.	K232838

Comparison of Technological Characteristics:

The subject device and predicate device have similar technological characteristics. The patient contacting implants of the subject device, predicate device and reference device are all manufactured from stainless steel. The subject wires are stainless steel and offered in a 1.6mm diameter. The subject stainless steel pins are offered in diameters of 2.0mm, 3.0mm while the primary predicate pins are offered in diameters of 2.0mm, 2.5mm, 3.0mm, 4.0mm, 5.0mm and 6.0mm. Lengths of the subject device pins are 60-100mm and fall within the range of the primary predicate pin lengths of 60-175mm. Both the subject device and the primary predicate device have external fixation non patient contacting rails that are manufactured from aluminum.

Non-Clinical Performance Testing Summary:

Testing was performed to compare the strength of the subject device to the predicate device per ASTM 1541. For biocompatibility, patient contacting implant materials are identical to those cleared in previous Paragon 28 510(k)s (K212895, K232838) and manufacturing methods do not impact biocompatibility endpoints. Sterilization parameters have been validated to accomplish a sterility assurance level (SAL) of 10^{-6} and the methods used to establish the sterility of the subject device are identical to the methods used to establish the sterility of other Paragon 28 External Fixation Systems (K212895, K232838). For the expanded indications for use of the subject device as compared to the predicate (Forefoot Arthrodesis as compared to Rear & Mid-Foot Arthrodesis), a secondary predicate was used to support fusions of the metatarsal.

Conclusion:

The performance data demonstrate that the subject device performs substantially equivalent to the predicate device that is currently marketed for same intended uses. The secondary predicate contains indications that are substantially equivalent to the subject device. The External Fixation Mini Rail System was demonstrated to be substantially equivalent to the predicate cited in the passage above with respect to indications, design, materials, function, manufacturing, and performance.