August 11, 2025

Paragon 28, Inc.
Jacqueline Sloan
Regulatory Affairs Specialist I
14445 Grasslands Drive
Englewood, Colorado 80112

Re: K251862
Trade/Device Name: External Fixation Bone Distractor
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: June 13, 2025
Received: June 17, 2025

Dear Jacqueline Sloan:

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.	K251862

Please provide the device trade name(s).

External Fixation Bone Distractor

Please provide your Indications for Use below.

The External Fixation Bone Distractor is intended for treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities.
The External Fixation Bone Distractor is indicated for adult and pediatric (greater than 2 through 21 years of age) patients.

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. 14445 Grasslands Dr. Englewood, CO 80112
Contact:	Jacqueline Sloan Regulatory Affairs Specialist I Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112 Phone: 720-617-6843 Jackie.Sloan@zimmerbiomet.com
Date Prepared:	August 08, 2025
Device Trade Name:	External Fixation Bone Distractor
Device Class and Common Name:	Class II, appliance, fixation, nail/blade/plate combination, multiple component
Classification:	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories.
Product Code:	KTT
Indications for Use:	The External Fixation Bone Distractor is intended for treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities. The External Fixation Bone Distractor is indicated for adult and pediatric (greater than 2 through 21 years of age) patients.
Device Description:	The Paragon 28 External fixation Bone Distractor is a transverse bone transport system designed to assist in the controlled movement of a bone segment across a defect. The device can be used independently or in conjunction with the Monkey Rings External Fixation System (K232838) or

Monkey Bars Pin to Bar External Fixation System (K242452) to form hybrid frames.

Primary Predicate: Truelok Elevate (K242861)

Reference Device A: Monkey Rings External Fixation System (K232838)

Reference Device B: Monkey Bars Pin to Bar External Fixation System (K242452)

Technological Comparison:

The subject device, the External Fixation Bone Distractor, and the predicate device, the TrueLok™ Elevate, share comparable technological characteristics. Both devices are intended for treating extremity conditions by facilitating the gradual formation and distraction of a tibial bone segment over a period of several days. Each incorporates serrated connection bolts to prevent rotational movement and loosening during clinical use. Additionally, both systems support customizable frame configurations to accommodate individual patient anatomy and clinical needs.

The subject device features a distractor with a travel length of 17 mm, compared to 14 mm in the predicate device. This minor difference does not raise different questions of safety or effectiveness, as both devices perform the same function of controlled bone segment transport.

The subject device features a distractor body with a 100mm long, 11mm diameter rod. Reference device A has 11mm threaded pillar lengths 30mm-300mm. The subject device and Reference Device A utilize the same threaded connection for connecting to circular rings.

Regarding fixation, the subject device accommodates half pins with thread diameters of 3 mm, 4 mm, and 5 mm, all with blunt tips, and lengths ranging from 150 mm to 200 mm. The predicate device uses 4 mm diameter half pins, 120 mm in length, with an 18 mm threaded portion.

These dimensional and design differences are minor and do not affect the intended use, performance, or safety profile of the device. The subject device utilizes the same half-pins as Reference device B. The subject device also uses the same pin clamping methods as Reference device B. Therefore, the pins do not raise different questions of safety or effectiveness.

Materials used in the subject device include stainless steel (ASTM F138 / AISI 316LVM) for the half pins—matching the predicate—as well as stainless steels (AISI 303, 304, 302, 420, 630), aluminum alloy (EN-AW 6082 T6), and Polyphenylsulfone (PPSU) polymer for frame components. Patient-contacting instruments are also made from stainless steel. All materials are biocompatible and commonly used in orthopedic devices.

Feature	Similarities	Differences	Explanation for Differences
Intended Use	Both the subject device and predicate (TrueLok Elevate, K242861) are designed to treat extremity conditions by facilitating the formation and gradual distraction of a tibial bone segment.	None	N/A
Connection Bolts	Both the subject device and predicate (TrueLok Elevate, K242861) incorporate serrated connection bolts to prevent rotational movement and loosening during clinical use.	None	N/A
Frame Configurations	Both the subject device and predicate (TrueLok Elevate, K242861) support customizable frame configurations to accommodate patient anatomy and clinical needs.	None	N/A
Distractor Travel Length	Both the subject device and predicate (TrueLok Elevate, K242861) perform controlled bone segment transport via distractors.	Subject device travel length: 17 mm; Predicate device (TrueLok Elevate, K242861) travel length: 14 mm.	The 3 mm longer travel length in the subject device does not impact safety or effectiveness as the function is equivalent.
Distractor Rod	Both the subject device and Reference Device A (K232838) have an 11 mm diameter rod.	Subject device rod length: 100 mm; Reference Device A (K232838) threaded pillar lengths range from 30 mm to 300 mm.	The difference in length allows flexibility; both use the same threaded connection ensuring mechanical compatibility.
Half Pins	Subject device and Reference Device B (K242452) use the same half pins.	Subject device half pins: 3, 4, and 5 mm diameters; lengths 150–200 mm, blunt tips. Predicate device (TrueLok Elevate, K242861) half pins: 4 mm diameter, 120 mm length, 18 mm threaded portion.	The dimensional differences are minor and do not affect performance, intended use, or safety. The subject device pins align with a reference device known to be safe and effective.
Pin Clamping Methods	Both the subject device and Reference Device B (K242452) use identical pin clamping methods.	None	N/A
Materials	Materials used in the subject device include stainless steel (ASTM F138 / AISI 316LVM) for the half pins—matching the predicate—as well as stainless steels (AISI 303, 304, 302, 420, 630), aluminum alloy (EN-AW 6082 T6), and PPSU polymer for frame components.	None- The stainless-steel material are the same for the pins in the subject device and the half pins for the predicate.	For the frame components. All materials are biocompatible and commonly used in orthopedic devices.

Performance Testing: No additional bench testing was performed for the subject device. Instead, a worst-case analysis was conducted using existing data from other components within the device system. The selected components represent the most mechanically demanding configurations, and their performance was evaluated in accordance with ASTM F1541-17. This approach was conducted under design control procedures, and a rationale for the selection of worst-case components was provided to ensure that the evaluation adequately addresses the mechanical performance of the entire system.

Conclusions: The External Fixation Bone Distractor has the same intended use and similar technological characteristics as the predicate device, the TrueLok™ Elevate (K242861). Differences in design do not raise different questions of safety or effectiveness.

No additional bench testing was performed. Instead, a worst-case analysis was conducted using existing data from mechanically demanding components within the system. Testing was performed per ASTM F1541-17 under design control procedures, with rationale provided to support the selected configurations.

The subject device is therefore considered substantially equivalent to the predicate device.