December 19, 2025

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

Re: K253613
Trade/Device Name: Monkey Rings External Ring Fixation 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: November 17, 2025
Received: November 18, 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2025.12.19 14:01:29 -05'00'

for 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.	K253613	?

Please provide the device trade name(s). ?

Monkey Rings External Ring Fixation System

Please provide your Indications for Use below. ?

The Monkey Rings™ External Fixation System is intended to be used in adults and 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).

The Monkey Rings External Ring Fixation System is intended to treat the following patient indications in pediatric patients and adults for the treatment and fixation of:

- Open and closed fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis, infected union, non-union, or malunion of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity (e.g., orthoplastic surgery)
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of comminuted intra-articular fractures
- Bone transport

The Monkey Rings External Ring Fixation System is indicated in adults for:

- Osteotomy
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Offloading and/or immobilization of ulcers and/or wounds of the foot and ankle
- Lisfranc dislocations
- Ankle distraction (arthrodiastasis)
- Septic fusion

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:	November 16, 2025
Device Trade Name:	Monkey Rings External Ring Fixation System
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 Monkey Rings™ External Fixation System is intended to be used in adults and 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). The Monkey Rings™ External Fixation System is indicated in adults and pediatric patients or the treatment and fixation of: • Open and closed fractures • Post-traumatic joint contracture which has resulted in loss of range of motion

• Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction

• Pseudoarthrosis, infected union, non-union, or malunion of long bones

• Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction

• Correction of bony or soft tissue deformity (e.g., orthoplastic surgery)

• Correction of segmental bony or soft tissue defects

• Joint arthrodesis

• Management of comminuted intra-articular fractures

• Bone transport

The Monkey Rings External Ring Fixation System is indicated in adults for:

• Osteotomy

• Revision procedure where other treatments or devices have been unsuccessful

• Bone reconstruction procedures

• Fusions and replantations of the foot

• Charcot foot reconstruction

• Offloading and/or immobilization of ulcers and/or wounds of the foot and ankle

• Lisfranc dislocations

• Ankle distraction (arthrodiastasis)

• Septic fusion

Device Description: The Monkey Rings External Ring Fixation System is a modular, ring-based external fixation system intended for the treatment and fixation of a variety of orthopedic conditions in pediatric and adult patients. The system is designed to stabilize bone segments during fracture management, deformity correction, or limb lengthening procedures. It consists of multiple components, including rings, connecting rods, struts, bolts, fasteners, clamps, plates, pins, and Kirschner wires (K-wires), which can be assembled in various configurations to provide either static fixation or gradual adjustment of bone position. The modular design allows surgeons to tailor the construct to meet specific anatomical and clinical needs.

The subject components included in this submission are the Universal Joint Struts and updated sterilization parameters for the system. The Universal Joint Strut is a newly introduced component designed to allow precise modification of strut length and controlled repositioning of the fixation rings over time. Its universal joint mechanism provides enhanced angular flexibility, enabling improved intraoperative adjustability and postoperative frame modification while maintaining structural stability and fixation integrity. All other components of the Monkey Rings External Ring Fixation System, including rings, connecting rods, and associated fixation hardware, were previously cleared and remain unchanged in design and function.

Primary Predicate: Paragon 28 External Ring Fixation System (K212895)

Reference Device: Taylor Spatial Frame (K201253)

Technological Comparison:

The subject device, Monkey Rings External Ring Fixation System, and the predicate device, the Paragon 28 External Ring Fixation System, share similar technological characteristics. Both systems consist of circular rings connected by adjustable struts, allowing precise multi-planar adjustments. Both use stainless steel or titanium pins and tensioned wires to secure the rings to bone, with optional hinges or joints to permit controlled joint movement. The struts on both devices are manually adjustable and include lockout mechanisms to maintain corrections and prevent unintended movement.

The primary difference between the subject device and the predicate device is the addition of a universal joint strut, which enables off-axis circular ring fixation for deformity correction. The universal joint strut can be adjusted to change its length, allowing the ring placement to be gradually modified over time. It also incorporates a lockout feature to control when lengthening or shortening occurs. Using six universal joint struts around a ring construct allows independent movement while maintaining overall frame stability, whereas the predicate device uses ball joint struts with locking ends to stabilize the frame.

The differences between design modifications amid the universal joint strut and the previous ball joint struts are minor and do not affect the intended use, performance, or safety profile. Therefore, they do not raise different questions of safety or effectiveness.

Table 1: Technological Comparison

Feature / Characteristic	**Subject Device: Monkey Rings External Fixation System**	**Predicate Device: Paragon 28 External Fixation System**	**Comparison / Notes**
Device Type	Circular external ring fixation system	Circular external ring fixation system	Same device type; intended for multi-planar deformity correction
Rings & Struts	Circular rings connected by adjustable struts; includes universal joint struts	Circular rings connected by adjustable struts; uses ball joint struts	Both allow precise multi-planar adjustment; subject device adds universal joint strut for off-axis fixation
Adjustable Mechanism	Manual struts with lockout mechanisms; universal joint allows controlled lengthening/shortening	Manual struts with lockout mechanisms; ball joint struts	Universal joint provides independent ring movement while maintaining frame stability; overall locking function remains comparable
Pins & Wires	Stainless steel or titanium pins; tensioned wires	Stainless steel or titanium pins; tensioned wires	Material and fixation method identical
Optional Hinges / Joints	Available for controlled joint movement	Available for controlled joint movement	Same functionality
Intended Use	Stabilization of fractures, osteotomies, and deformity corrections	Stabilization of fractures, osteotomies, and deformity corrections	No change in intended use
Safety / Performance Impact	Addition of universal joint strut; minor design changes	Original design	Differences do not affect safety, performance, or raise different questions of effectiveness
Lockout Feature	Yes, on all struts including universal joint	Yes, on all struts	Functionally similar; subject device offers added off-axis capability

Performance Testing:

ASTM F1541-17 – Static Axial Grip of Connector (A2), Static Torsional Grip of Connectors and Fixators (A2 and A3), Static Compression of Rings (A3), Dynamic Axial Compression of Construct (A7), Evaluation of Bending and Torsional Strength of Pins (A5), Evaluation of Static Compression of Subassembly (A6).

The performance of these configurations was assessed in accordance with ASTM F1541-17 under established design control procedures. In addition, a comprehensive sterilization assessment, documented in TR-23080701, was completed to confirm that the selected sterilization process achieves the required sterility assurance level and that the device maintains its material, mechanical, and functional integrity following sterilization. These activities collectively demonstrate that the evaluation methods are appropriate and sufficient to support the safety and performance of the subject device.

Conclusions:

The Monkey Rings External Ring Fixation System has the same intended use and similar technological characteristics as the predicate device, the Paragon 28 External Ring Fixation System (K212895). Differences in design do not raise different questions of safety or effectiveness. The subject device is therefore considered substantially equivalent to the predicate device.