October 12, 2023

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

Re: K232838
Trade/Device Name: Monkey Rings™ External 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: September 13, 2023
Received: September 14, 2023

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232838

Device Name

Monkey Rings™ External Fixation System

Indications for Use *(Describe)*

The Monkey Rings™ External Fixation System is indicated 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 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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name: Monkey Rings™ External Fixation System

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

Contact: Edward Wells-Spicer
Regulatory Affairs Specialist
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
ewspicer@paragon28.com

Date Prepared: October 12, 2023

Classifications: 21 CFR §888.3030

Class: II

Product Codes: KTT

Indications for Use:
The Monkey Rings™ External Fixation System is indicated 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 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 Fixation System is a modular, ring-based, external fixation system designed for the treatment and fixation of a variety of conditions in pediatric and adult patients. The Monkey Rings™ External Fixation System utilizes wires, pins, struts, rods, bolts, fasteners, clamps, and plates that connect to rings statically placed or gradually manipulated in order to fixate or correct the bone. The modular design of the system allows for a customized treatment for the patient.

Components of the Monkey Rings™ External Fixation System may be used in conjunction with all Paragon 28 legally marketed devices.

The components of the device are offered in a variety of sizes, which allow for a truly customized external fixation device.

Predicate Device:

Table 1: Predicate Device

Device Name(s)	Manufacturer	K-Number
Paragon 28 External Ring Fixation System	Paragon 28, Inc.	K212895

Reference Device:

Table 2: Reference Device

Device Name(s)	Manufacturer	K-Number
Modular Rail System, TAYLOR SPATIAL FRAME External Fixator, JET-X Fixator, ILIZAROV External Fixator, Other External Fixation	Smith & Nephew	K201253

Non-Clinical Performance Testing Summary:
An engineering analysis of bending strength was conducted to provide evidence that the original testing and subsequent performance is not adversely affected by the modifications to the subject devices. For biocompatibility, both materials are identical to materials cleared in Paragon 28 External Ring Fixation System (K212895) and differences in 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 are identical to the methods used to establish the sterility of the Paragon 28 External Ring Fixation System in K212895.

Substantial Equivalence Discussion:
The subject device is similar to the predicate device for technological characteristics. The differences between the subject device and predicate are the addition of longer wires, new titanium alloy wires and updated sterilization parameters. Indications are identical between the subject device and predicate. In support of the claim of substantial equivalence the comparison between the subject and predicate system demonstrates a shared use of material, fundamental design, and general operating principles.

Conclusion:
The performance data demonstrate that the subject device performs substantially equivalent to the predicate devices that are currently marketed for the same intended use. The Monkey Rings™ External Fixation 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.