November 8, 2021

Paragon 28, Inc
Haylie Hertz
Regulatory Affairs Specialist
14445 Grasslands Dr.
Englewood, Colorado 80112

Re: K212895
Trade/Device Name: Paragon 28 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: September 9, 2021
Received: September 10, 2021

Dear Haylie Hertz:

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 (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 located 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.

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

80 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint Arthroplaty 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.

510(k) Number *(if known)*

K212895

Device Name
Paragon 28 External Ring Fixation System

Indications for Use *(Describe)*

The Paragon 28 External Ring 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 Paragon 28 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

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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7 510(k) Summary

Device Trade Name: Paragon 28 External Ring Fixation System

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

Contact: Ms. Haylie Hertz
Regulatory Affairs Specialist
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
hhertz@paragon28.com

Date Prepared: September 9, 2021

Classifications: 21 CFR §888.3030

Class: II

Product Codes: KTT

Indications for Use:
The Paragon 28 External Ring 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
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- Pseudoarthrosis, infected union, non-union, or malunion of long bones
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- Ankle distraction (arthrodiastasis)
- Septic fusion

Device Description:
The Paragon 28 External Ring 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 Paragon 28 External Ring 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 Paragon 28 External Ring 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.

Primary Predicate Device:

Table 2: Primary Predicate Devices

Device Name(s)	Manufacturer	K-Number
Hoffmann LRF System	Stryker	K203568

Reference Predicate Device:

Table 3: Reference Predicate Devices

Device Name(s)	Manufacturer	K-Number
RingFIX System	Small Bone Innovations (SBi)	K071394
MAXFRAME Multi-Axial Correction System	DePuy Synthes	K161417

Performance Testing Summary:
Non-clinical testing on the components and full Paragon 28 External Ring Fixation System has been performed in accordance with ASTM F1541.

Comparison of Technological Characteristics:
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 Paragon 28 External Ring 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.