November 1, 2024

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

Re: K242452
Trade/Device Name: Monkey Bars Pin to Bar 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: August 16, 2024
Received: August 19, 2024

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242452

Device Name
Monkey Bars Pin to Bar External Fixation System

Indications for Use *(Describe)*
The Monkey Bars Pin to Bar External Fixation System is intended to be used in adult and pediatric patients (specifically, children and adolescents aged 2 through 21 years) for provisional fixation of open and/or unstable fractures in the lower and upper extremities and pelvis. It may also be used for temporary fixation of peri-articular or intra-articular fractures. Additionally, the device can be used on fractures where soft tissue injury or an infected fracture site may preclude the use of other fracture fixation treatments.

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.

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510(K) SUMMARY

Manufacturer:	Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112
Contact:	Edward Wells-Spicer Regulatory Affairs Specialist II Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112 Phone: 720-994-5481 ewspicer@paragon28.com
Date Prepared:	October 31, 2024
Device Trade Name:	Monkey Bars Pin to Bar External Fixation System
Device Class and Common Name:	Class II, External Fixation System
Classification:	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories.
Product Code:	KTT
Indications for Use:	The Monkey Bars Pin to Bar External Fixation system is intended to be used in adult and pediatric patients (specifically, children and adolescents aged 2 through 21 years) for provisional fixation of open and/or unstable fractures in the lower and upper extremities and pelvis. It may also be used for temporary fixation of peri-articular or intra-articular fractures. Additionally, the device can be used on fractures where soft tissue injury or an infected fracture site may preclude the use of other fracture fixation treatments.
Device Description:	The device is used for the external stabilization of bone fractures. It consists of: Carbon fiber composite bars, 11mm diameter by 150mm to 500mm lengths, titanium combination clamp, aluminum 5 & 8 hole multi-pin clamps, aluminum straight and 30 degree angled posts, stainless steel 3mm, 4mm

and 5mm thread diameter pins with 5mm diameter shanks that come in blunt tip and self tapping with 125mm through 230mm overall lengths and 20mm through 65mm thread lengths, stainless steel transfixing pin with 5mm shank, 7.2mm thread diameter, and 325mm overall length, and stainless steel instruments for implantation. The pins are implanted into bone and then they are connected using the clamps, rods and posts to form a rigid construct which holds the bone fragments rigidly in place. The pins are offered in various lengths and thicknesses.

Primary Predicate: OIC External Fixation System (K211112)

Additional Predicate: Orthofix Galaxy Fixation System (K113770)

Reference Device: Monkey Rings External Fixation System (K212895)

Substantial Equivalence: The Monkey Bars Pin to Bar External Fixation System is substantially equivalent to the legally marketed predicate device systems with respect to intended use and design. The subject Monkey Bars Pin to Bar External Fixation System is similar to the cleared OIC External Fixation System in terms of material, shape, and dimensions.

The primary difference between the subject Monkey Bars Pin to Bar External Fixation System and the primary predicate device is that the jaw can rock in both directions as it closes on either the bar or pin. The subject device has a shorter bar length range, a larger combination clamp design and size, and a longer kickstand (with one predicate size being wider). The subject device pins have a shorter length range and have the same diameter as the primary predicate pins.

The differences in technological characteristics between the subject device and predicate device were shown not to introduce different questions of safety and effectiveness.

Performance Testing: All necessary testing has been performed on representative Monkey Bars components to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended. Clinical data are not needed to support the safety and effectiveness of the subject device. Minimal Construct Static Compression Testing was performed.

Conclusions: The Monkey Bars Pin to Bar External Fixation System subject to this submission possesses the same intended use and has similar technological characteristics as the predicate device system components. All performance testing conducted for the Monkey Bars Pin to Bar External Fixation System predetermined acceptance criteria or were otherwise considered acceptable. As such, the Monkey Bars Pin to Bar External Fixation System are substantially equivalent to the predicate devices.