December 25, 2021

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

Re: K211770
Trade/Device Name: R3ACT™ Stabilization System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN, MBI
Dated: June 4, 2021
Received: June 8, 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

801 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,

for

Laura C. Rose, PhD
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K211770

Device Name
R3ACT™ Stabilization System

Indications for Use *(Describe)*

The R3ACT™ Stabilization System is intended as an adjunct in fracture repair and ligamentous injuries of small bones of the feet and ankles including the distal tibia, distal fibula, talus, and calcaneus, and as an adjunct in external and intramedullary fixation systems involving plates and rods. Specifically, the R3ACT™ Stabilization System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

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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Paragon 28, Inc.

# 510(K) SUMMARY

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| **510(k) Number:** | K211770 |
| **Manufacturer:** | Paragon 28, Inc.<br>14445 Grasslands Dr.<br>Englewood, CO 80112 |
| **Contact:** | Haylie Hertz<br>Senior Regulatory Affairs Specialist<br>Paragon 28, Inc.<br>14445 Grasslands Dr.<br>Englewood, CO 80112<br>Phone: 303-720-0017<br>hhertz@paragon28.com |
| **Date Prepared:** | December 23, 2021 |
| **Device Trade Name:** | R3ACT™ Stabilization System |
| **Device Class and Common Name:** | Class II, Syndesmosis Repair Device |
| **Classification:** | Primary – 21 CFR 888.3040: Single/multiple component metallic bone fixation appliances and accessories.<br>Secondary – 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories. |
| **Product Codes:** | Primary – HWC<br>Secondary – HTN, MBI |
| **Indications for Use:** | The R3ACT™ Stabilization System is intended as an adjunct in fracture repair and ligamentous injuries of small bones of the feet and ankles including the distal tibia, distal fibula, talus, and calcaneus, and as an adjunct in external and intramedullary fixation systems involving plates and rods. Specifically, the R3ACT™ Stabilization System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures. |
| **Device Description:** | The R3ACT™ Stabilization System is a fixation device comprised of a titanium alloy screw, UHMWPE suture, and a polyurethane component. It is provided in various sizes to |

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| | accommodate patient anatomy. The device maintains fixation prior to weight bearing and then allows motion after weight bearing.<br>The implants can be used in conjunction with the Baby Gorilla®/Gorilla® Plating System (K203511). |
| **Predicate Device:** | FibuLink Syndesmosis Repair System (K173550) |
| **Additional Predicates:** | Baby Gorilla®/Gorilla® Plating System (K203511)<br>TRIMit Screw System (K041189)<br>ZipTight System (K130033) |
| **Substantial Equivalence:** | The R3ACT™ Stabilization System is substantially equivalent to the legally marketed predicate device with respect to intended use and design. The subject system shares the same materials (titanium and UHMWPE), features, and intended use. Differences in materials (polyurethane), design, sizing, and manufacturing were shown not to introduce new questions of safety and effectiveness. |
| **Performance Testing:** | All necessary testing has been performed on representative R3ACT™ Stabilization System components to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended. All testing was performed on finished devices.<br>The device performance was characterized via torque to failure, insertion and removal torque, static pullout, static bending, static axial dissociation, and dynamic axial dissociation testing.<br>Bacterial endotoxin testing was also conducted and the test results meet acceptance criteria.<br>Clinical data are not needed to support the safety and effectiveness of the subject device. |
| **Conclusions:** | The R3ACT™ Stabilization System subject to this submission possess the same intended use and technological characteristics as the predicate device system components. All performance testing conducted for the R3ACT™ Stabilization System met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the R3ACT™ Stabilization System components are substantially equivalent to the predicate device for the intended use. |