August 30, 2021

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

Re: K211322
Trade/Device Name: Paratrooper™ Plantar Plate Repair System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 29, 2021
Received: August 3, 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); 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,

Laura C. Rose, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211322

Device Name
Paratrooper™ Plantar Plate Repair System

Indications for Use *(Describe)*
The Paratrooper™ Plantar Plate Repair System is intended for fixation of tissue to bone and tissue to tissue. Specific indications:

Foot/ankle:
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair
- Metatarsal Ligament and Tendon Repair
- Hallux Valgus Reconstruction
- Digital Tendon Transfers
- Mid-foot Reconstruction
- Plantar Plate Repair

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

510(k) Number:	K211322
Device Trade Name:	Paratrooper™ Plantar Plate Repair System
Manufacturer:	Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112
Contact:	Haylie Hertz Phone: 303-720-0017 hhertz@paragon28.com
Date Prepared:	August 30, 2021
Common Name:	Soft Tissue and Bone Fixation Fastener
Classification:	21 CFR 888.3040
Class:	II
Product Code:	MBI
Predicate Device:	Paratrooper™ Plantar Plate Repair System (K191227)
Reference Device:	ICONIX All Suture Anchor System (K133671)

Indications for Use:
The Paratrooper™ Plantar Plate Repair System is intended for fixation of tissue to bone and tissue to tissue. Specific indications:

Foot/ankle:

- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair
- Metatarsal Ligament and Tendon Repair
- Hallux Valgus Reconstruction
- Digital Tendon Transfers
- Mid-foot Reconstruction
- Plantar Plate Repair

Device Description:
The Paratrooper™ Plantar Plate Repair System includes an all-suture soft tissue fixation device. The suture implant comes in one size and is provided attached to a needle or preloaded on an inserter.

Substantial Equivalence:
The intended use of the modified device, as described in its labeling, has not changed as a result of the modifications proposed in the present submission. In addition, the subject device possesses the same technological characteristics as the predicate device, including performance, basic design, material, sterilization and sizes. Differences between the Paratrooper™ Plantar Plate Repair System and the predicate device (implantation technique, anchor interconnection, dyes, and manufacturing) were shown not to raise new questions of safety and effectiveness. Therefore, the Paratrooper™ Plantar Plate Repair System is substantially equivalent to the predicate device cited on the previous page with respect to indications, design, function, and performance.

Performance Testing:
All necessary testing has been performed on representative Paratrooper™ Plantar Plate Repair System components to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended. All testing was performed on finished devices. The device performance was characterized via mechanical performance testing and usability testing. Bacterial endotoxin testing was also conducted and the device was found to meet the established limits.

Clinical Testing:
Clinical testing was not necessary to support equivalence.

Conclusion:
The Paratrooper™ Plantar Plate Repair System possesses the same intended use and technological characteristics as the predicate device. Therefore, the Paratrooper™ Plantar Plate Repair System is substantially equivalent for its intended use.