January 24, 2020

Paragon 28, Inc.
Eric Lintula
Director of Regulatory Affairs
4B Inverness Ct. E, STE 280
Englewood, Colorado 80112

Re: K191227
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: December 23, 2019
Received: December 23, 2019

Dear Mr. Lintula:

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,

for

Laura Rose, Ph.D.
Acting 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)*
K191227

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.

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510(k) Summary

Date:	May 3rd, 2019
510(k) Number:	K191227
Sponsor:	Paragon 28, Inc. 14445 Grasslands Dr. Englewood, Colorado 80112 Phone: (888) 728-1888 Fax: (888) 728-1220
Sponsor contact:	Eric Lintula, Senior Director of Quality and Regulatory Affairs
Trade Name:	Paratrooper™ Plantar Plate Repair System
Regulatory Class:	Class II
Regulation, Product Code, Classification, and Common Name:	888.3040, MBI, Fastener, Fixation, Nondegradable, Soft Tissue
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.
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
Materials:	The Paratrooper™ Plantar Plate Repair System implants are made from ultra-high-molecular-weight-polyethylene (UHMWPE) co-braid suture, and polyester. All suture meets all surgical suture requirements established by the USP for non-absorbable surgical sutures except for oversized diameter. The instrumentation is manufactured from medical grades of stainless steel, nitinol, and polymer.
Primary Predicate:	K133671, Stryker Endoscopy ICONIX All Suture Anchor System
Additional Predicate:	K162429, Ziptek, LLC ZipE® Knotless Tissue Repair and Attachment Device
Reference Device:	K181774, Teleflex Medical Force Fiber® Sutures

Comparison to Predicate Indications:	The subject Paratrooper™ Plantar Plate Repair System and Stryker ICONIX All Suture Anchor are intended to be used for tissue to bone fixation. The subject Paratrooper™ Plantar Plate Repair System and Ziptek ZipE® device are intended to be used for tissue to tissue fixation. All indications for the subject device are within the indications of the predicate devices.
Comparison to Predicate Technological Characteristics:	The subject Paratrooper™ Plantar Plate Repair System components possess the same technological characteristics as the predicate devices. These include: • performance, • basic design, • material, manufacturing and • sizes (dimensions are comparable to those offered by the predicate systems). Differences between the Paratrooper™ Plantar Plate Repair System implants and the predicate devices were shown not to raise new questions of safety and effectiveness. Therefore, the fundamental scientific technology of the subject Paratrooper™ Plantar Plate Repair System components is similar to previously cleared devices.
Performance Data:	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 pullout testing. Additional testing includes pyrogenicity, biocompatibility and sterilization. Clinical data are not needed to support the safety and effectiveness of the subject device.
Conclusion:	Performance testing demonstrates the substantial equivalence of the Paratrooper™ Plantar Plate Repair System to the Stryker ICONIX All Suture Anchor System and the Ziptek ZipE® Knotless Tissue Repair and Attachment Device. Therefore, the Paratrooper™ Plantar Plate Repair System is substantially equivalent to the predicate devices with respect to their indications for use, technical characteristics, and function.