March 17, 2026

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

Re: K253886
Trade/Device Name: Grappler Suture Anchor PCFD Tether System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 5, 2026
Received: January 5, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253886

Please provide the device trade name(s).

Grappler Suture Anchor PCFD Tether System

Please provide your Indications for Use below.

The Grappler Suture Anchor PCFD Tether System is intended for the fixation of soft tissue to bone including:

Foot/Ankle: Medial Stabilization (Deltoid and Spring Ligament Repair for addressing Progressive Collapsing Foot Deformity), Hindfoot Repair (Correction of Peritalar Subluxation/Dislocation, Hindfoot Valgus Deformity or Subfibular Impingement for Addressing Progressive Collapsing Foot Deformity), Interosseous Talocalcaneal Ligament Repair to address Progressive Collapsing Flatfoot Deformity

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

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

Contact: Edward Wells-Spicer
Senior Regulatory Affairs Specialist
Paragon 28, Inc.
14445 Grasslands Dr.
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Phone: 720-994-5481
ewspicer@paragon28.com

Date Prepared: March 13, 2026

Device Trade Name: Grappler Suture Anchor PCFD Tether System

Device Class and Common Name: Class II, Fastener, Fixation, Nondegradable, Soft Tissue

Classification: 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener

Product Codes: MBI

Indications for Use: The Grappler Suture Anchor PCFD Tether System is intended for the fixation of soft tissue to bone including:

Foot/Ankle: Medial Stabilization (Deltoid and Spring Ligament Repair for addressing Progressive Collapsing Foot Deformity), Hindfoot Repair (Correction of Peritalar Subluxation/Dislocation, Hindfoot Valgus Deformity or Subfibular Impingement for Addressing Progressive Collapsing Foot Deformity), Interosseous Talocalcaneal Ligament Repair to address Progressive Collapsing Flatfoot Deformity

Device Description: The Grappler Suture Anchor PCFD Tether System consists of suture anchors, suture, and the accompanying instrumentation for the intended use of soft tissue damage repair. The subject PCFD Tether line extension consists of

	two PEEK suture anchors connected by UHMWPE suture. The talar anchor diameter is ⌀4.5mm and the calcaneal anchor diameter is ⌀3.5mm, the length of each anchor is 12mm. The suture tape is a doubled-over USP 2 equivalent tape. The implant construct comes pre-loaded on two inserter handles. Device specific drill guides are provided for tunnel creation.
Predicate Device:	Grappler Suture Anchor R3FLEX IOL System (K240594)
Additional Predicate Device:	Grappler Interference Screw System (K241864)
Additional Predicate Device:	Grappler Suture Anchor System (K211002)
Substantial Equivalence:	The proposed Grappler Suture Anchor PCFD Tether System are substantially equivalent to the primary predicate Grappler Suture Anchor R3FLEX IOL System (K240594), additional predicate Grappler Interference Screw System (K241864) and additional predicate Grappler Suture Anchor System (K211002) with respect to indications, design, material and function. The difference in indications between the subject and primary predicate device are the addition of indications specific to the correction of Progressive Collapsing Foot Deformity (PCFD), and similar indications for the treatment of PCFD are held by the additional predicate Grappler Interference Screw System (K241864). Technological differences between the subject device and primary predicate are that the subject device contains two PEEK cortical buttons that extend into the cortical bone, and the subject device technique orients placement of buttons in different planes in the foot to accommodate PCFD use. Implant material of the subject device and additional predicate Grappler Interference Screw System are both PEEK.
Performance Testing:	Engineering analysis is presented to provide evidence that the original testing and subsequent performance is not adversely affected by the modifications to the subject devices. Specifically, an analysis was presented for Suture Abrasion and Dynamic Axial Dissociation Testing. Comparative testing was performed against the additional predicate Grappler Interference Screw System (K241864) including static and fatigue tensile testing evaluating load and displacement.

The results of this testing demonstrate the subject device is substantially equivalent to the predicate devices. Bacterial endotoxin testing was conducted and the test results meet acceptance criteria of FDA recognized standards.

Conclusions:

The Grappler Suture Anchor PCFD Tether System subject to this submission possesses the same intended use and similar technological characteristics as the predicate device system components. Indications have been modified for the subject device as compared to the predicate device, but are similar to the additional predicate Grappler Interference Screw System. All performance testing conducted for the Grappler Suture Anchor PCFD Tether System met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the Grappler Suture Anchor PCFD Tether System components are substantially equivalent to the predicate devices for the intended use.