August 3, 2026

Paragon 28, Inc.
Brittanie Dogue
Regulatory Affairs Specialist II
14445 Grasslands Dr.
Englewood, Colorado 80112

Re: K262047
Trade/Device Name: Grappler Suture Anchor 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 31, 2026
Received: July 31, 2026

Dear Brittanie Dogue:

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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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.

K262047

Please provide the device trade name(s).

Grappler Suture Anchor System

Please provide your Indications for Use below.

The Grappler Suture Anchor System is intended for the fixation of soft tissue to bone including:
Elbow: Biceps Tendon Reattachment, Lateral Epicondylitis Repair, Tennis Elbow Repair
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair
Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC
Foot/Ankle: Lateral Stabilization (Brostrom, Brostrom-Gould, Chrisman-Snook Repair), Ankle Ligament Repair, Medial Stabilization (Deltoid Repair, Spring Ligament Reconstruction), Achilles Tendon Repair, Metatarsal Ligament Repair, Syndesmosis Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, LisFranc Repair
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Extra Capsular Reconstruction, Patellar Ligament and Tendon Avulsion Repair
Hip: Capsular Repair, Acetabular Labral Repair

The plate interacting anchors are only indicated for the above Hand/Wrist and Foot/Ankle indications.

The 3.5mm Primatix Anchor is only indicated for the below Foot/ankle indications.
Foot/Ankle: Lateral Stabilization (Brostrom, Brostrom-Gould, Chrisman-Snook Repair), Ankle Ligament Repair, Medial Stabilization (Deltoid Repair, Spring Ligament Reconstruction), Metatarsal Ligament Repair, Syndesmosis Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, LisFranc Repair.

The Mpire Knotless Suture Anchor System is intended for the fixation of soft tissue to bone including:
Foot/Ankle: Lateral Stabilization (Brostrom, Brostrom-Gould, Chrisman-Snook Repair), Ankle Ligament Repair, Medial Stabilization (Deltoid Repair, Spring Ligament Reconstruction), Achilles Tendon Repair, Metatarsal Ligament Repair, Syndesmosis Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, LisFranc Repair

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [x] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(K) SUMMARY

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

Contact: Brittanie Dogué
Regulatory Affairs Specialist II
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
Phone: 720-808-7119
Brittanie.dogue@zimmerbiomet.com

Date Prepared: August 03, 2026

Device Trade Names: Grappler Suture Anchor

Device Class: Class II

Primary Predicate(s): Grappler Suture Anchor (K211002)

Device Description: The GRAPPLER™ Suture Anchor System consists of suture anchors, suture, and the accompanying instrumentation for the intended use of soft tissue damage repair. The anchors are provided in PEEK, titanium, and suture materials in multiple sizes and lengths. Each anchor is accompanied by round suture or suture tape composed of UHMWPE and PGLA.

Classification and Product Codes:

21 CFR 888.3040; Smooth or threaded metallic bone fixation fastener.	MBI

Indications for Use:

The Grappler® Suture Anchor System is intended for the fixation of soft tissue to bone including:
Elbow: Biceps Tendon Reattachment, Lateral Epicondylitis Repair, Tennis Elbow Repair
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair
Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC
Foot/Ankle: Lateral Stabilization (Brostrom, Brostrom-Gould, Chrisman-Snook Repair), Ankle Ligament Repair, Medial Stabilization (Deltoid Repair, Spring Ligament Reconstruction), Achilles Tendon Repair, Metatarsal Ligament Repair, Syndesmosis Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, LisFranc Repair
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Extra Capsular Reconstruction, Patellar Ligament and Tendon Avulsion Repair
Hip: Capsular Repair, Acetabular Labral Repair

The plate interacting anchors are only indicated for the above Hand/Wrist and Foot/Ankle indications.

The 3.5mm Primatix Anchor is only indicated for the below Foot/ankle indications.
Foot/Ankle: Lateral Stabilization (Brostrom, Brostrom-Gould, Chrisman-Snook Repair), Ankle Ligament Repair, Medial Stabilization (Deltoid Repair, Spring Ligament Reconstruction), Metatarsal Ligament Repair, Syndesmosis Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, LisFranc Repair

The Mpire Knotless Suture Anchor System is intended for the fixation of soft tissue to bone including:
Foot/Ankle: Lateral Stabilization (Brostrom, Brostrom-Gould, Chrisman-Snook Repair), Ankle Ligament Repair, Medial Stabilization (Deltoid Repair, Spring Ligament Reconstruction), Achilles Tendon Repair, Metatarsal Ligament Repair, Syndesmosis Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, LisFranc Repair

Substantial Equivalence:

The Grappler Suture Anchor System is substantially equivalent to the legally marketed predicate device systems with respect

to the intended use, principle of operation and fundamental scientific technology.

The purpose of this submission is to add line extension of the Mpire and Primatix anchors. The differences between the subject devices and the predicate device include a smaller diameter and shorter length, incorporation of an anchor fork tip, and a 2-piece assembly design.

Performance Testing: All necessary testing has been performed on representative Grappler Suture Anchor 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 torsional; strength, insertion/removal torque, and static and fatigue tensile testing per ASTM F3690-24. Clinical data is not needed to support the safety and effectiveness of the subject device.

Conclusions: The subject device possesses similar indications for use, technological characteristics, and principles of operation as the predicate. All performance testing conducted for the Grappler Sture Anchor System met the predetermined acceptance criteria. As such, the Grappler Suture Anchor System components are substantially equivalent to the predicate devices for the intended use.