July 25, 2024

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

Re: K241864
Trade/Device Name: Grappler Interference Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 27, 2024
Received: June 27, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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.

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,

Robert M. Stefani -S
2024.07.25 09:22:41 -04'00'

For: Jesse Muir, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241864

Device Name

Grappler Interference Screw System

Indications for Use *(Describe)*

The Grappler Interference Screw System is intended for soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue and tendon transfers in surgeries of the shoulder, elbow, knee, foot/ankle, and hand/wrist. Specifically:

Shoulder:
- Rotator Cuff Repairs
- Bankart Repair
- SLAP Lesion Repair
- Biceps Tenodesis
- Acromio-Clavicular Separation Repair
- Deltoid Repair
- Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle:
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair
- Hallux Valgus Reconstruction
- Midfoot Reconstruction (e.g. reconstruction of the Spring Ligament to address Progressive Collapsing Flatfoot Deformity)
- Hindfoot Reconstruction (e.g. reconstruction of the Interosseous Talocalcaneal Ligament and/or Spring Ligament to address Progressive Collapsing Flatfoot Deformity)
- Metatarsal Ligament Repair
- Flexor Hallucis Longus Transfer for Achilles Tendon Reconstruction, and
- Flexor Digitorum Longus Transfer for Posterior Tibial Tendon Reconstruction.

Knee:
- Anterior Cruciate Ligament Repair
- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Patellar Tendon Repair
- Posterior Oblique Ligament Repair
- Illiotibial Band Tenodesis

Elbow:
- Biceps Tendon Reattachment
- Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist:
- Scapholunate Ligament Reconstruction
- Ulnar Collateral Ligament Reconstruction
- Radial Collateral Ligament Reconstruction
- Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
- Carpal Ligament Reconstructions and repairs
- Ligament Reconstruction and Tendon Interposition.

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

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

Contact: Edward (E.J.) Wells-Spicer
Regulatory Affairs Specialist II
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
Phone: 720-994-5481
ewspicer@paragon28.com

Date Prepared: June 27, 2024

Device Trade Name: Grappler Interference Screw 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 Interference Screw System is intended for soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue and tendon transfers in surgeries of the shoulder, elbow, knee, foot/ankle, and hand/wrist. Specifically:

Shoulder:

- Rotator Cuff Repairs
- Bankart Repair
- SLAP Lesion Repair
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Foot/Ankle:

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- Medial Stabilization

- Achilles Tendon Repair
- Hallux Valgus Reconstruction
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Elbow:

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Hand/Wrist:

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- Radial Collateral Ligament Reconstruction
- Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
- Carpal Ligament Reconstructions and repairs
- Ligament Reconstruction and Tendon Interposition.

Device Description: The Grappler Interference Screw System in composed of a screw manufactured from polyetheretherketon (PEEK). They are fully threaded, cannulated anchors with a flat head. The screws are provided in multiple lengths and sizes to accommodate variations in patient anatomy.

Predicate Device: Grappler Interference Screw System (K183690)

Substantial Equivalence: The Grappler Interference Screw System is substantially equivalent to the primary predicate Grappler Interference Screw System (K183690) with respect to design, material and function. The indications are for the subject Grappler

Interference Screw System fall within the intended use of the predicate Grappler Interference Screw System. No new risks are introduced to the patient as a result of adding more specific indications.

Performance Testing: All necessary testing has been performed on representative Grappler Interference Screw System Screw 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 Static Torsion, Static Insertion and Removal Torque, and Static Axial Pullout Testing per ASTM F543. Clinical data are not needed to support the safety and effectiveness of the subject devices.

Conclusions: The Grappler Interference Screw System subject to this submission possesses the same intended use and technological characteristics as the predicate device system. As such, the subject Grappler Interference Screw System components are substantially equivalent to the predicate devices for the intended use.