



March 26, 2024

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

Re: K240594

Trade/Device Name: Grappler Suture Anchor R3FLEX IOL System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 1, 2024
Received: March 4, 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,

Jesse Muir -S Digitally signed by Jesse Muir -S
Date: 2024.03.26 11:47:04 -04'00'

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

Indications for Use

Submission Number (if known)

K240594

Device Name

Grappler Suture Anchor R3FLEX IOL System

Indications for Use (Describe)

The Grappler Suture Anchor R3FLEX IOL 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, Christman-Snook Repair), Ankle Ligament Repair, Medial Stabilization (Deltoid, Spring Ligament Repair), 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.

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.

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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: March 21, 2024

Device Trade Name: Grappler Suture Anchor R3FLEX IOL 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 R3FLEX IOL 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

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Medial Stabilization (Deltoid, Spring Ligament Repair), 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.

Device Description: The Grappler Suture Anchor R3FLEX IOL System consists of suture anchors, suture, and the accompanying instrumentation for the intended use of soft tissue damage repair. The anchors are provided in titanium and all-suture and are connected by suture composed of UHMWPE.

Predicate Device: Grappler Suture Anchor R3FLEX IOL System (K223589)

Secondary Predicate Device: Grappler Suture Anchor System (K211002)

Substantial Equivalence: The Grappler Suture Anchor R3FLEX IOL System are substantially equivalent to the primary predicate Grappler Suture Anchor R3FLEX IOL System (K223589) and secondary predicate Grappler Suture Anchor System (K211002) with respect to indications, design, material and function.

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. 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 R3FLEX IOL System subject to this submission possesses the same intended use and

technological characteristics as the predicate device system components. All performance testing conducted for the Grappler Suture Anchor R3FLEX IOL System met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the Grappler Suture Anchor R3FLEX IOL System components are substantially equivalent to the predicate devices for the intended use.