March 3, 2023

Paragon 28, Inc.
Haylie Hertz
Sr. Regulatory Affairs Specialist
14445 Grasslands Dr.
Englewood, Colorado 80112

Re: K223589
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: February 1, 2023
Received: February 2, 2023

Dear Haylie Hertz:

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,

Melissa A. Ramcharan -S

For,

Laura C. Rose, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223589

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.

510(K) SUMMARY

K223589

Manufacturer:	Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112
Contact:	Haylie Hertz Sr. Regulatory Affairs Specialist Paragon 28, Inc. 14445 Grasslands Dr. Englewood, CO 80112 Phone: 303-720-0017 hhertz@paragon28.com
Date Prepared:	March 3, 2023
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 *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.
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 System (K222091, K211002)
Additional Predicate Device:	R3ACT Stabilization System (K211770)
Reference Devices:	Baby Gorilla®/Gorilla® Plating System (K222194),
Substantial Equivalence:	The proposed Grappler Suture Anchor R3FLEX IOL System are substantially equivalent to the predicate Grappler Suture Anchor System (K222091) 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, Dynamic Axial Dissociation Testing and a USP Monograph. 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.