February 11, 2021

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

Re: K203385
Trade/Device Name: TenoTac® Soft Tissue Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 13, 2020
Received: November 18, 2020

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203385

Device Name
TenoTac® Soft Tissue Fixation System

Indications for Use *(Describe)*
The TenoTac® Soft Tissue Fixation System is intended to be used for soft tissue to bone fixation.
Specific indications for the TenoTac® device include:

Foot & Ankle: Medial/lateral repair and reconstruction, mid and forefoot repair, hallux valgus repair, hallux malleus repair and reconstruction, metatarsal ligament/tendon repair and reconstruction including plantar plate attenuation and tear, and the correction of hammer toe, claw toe, mallet toe, crossover toe, floating toe, and any other lesser toe deformities, correction of metatarsophalangeal joint instability due to shortening from interphalangeal fusion, correction of metatarsophalangeal joint instability due to shortening from Weil osteotomy, Achilles tendon repair.

Hand & Wrist: Collateral ligament repair, Scapholunate ligament reconstruction, tendon transfers in phalanx, Volar plate reconstruction.

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

510(k) Number: K203385

Device Trade Name: TenoTac® Soft Tissue Fixation System

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

Contact: Haylie Hertz
Regulatory Affairs Specialist
Paragon 28, Inc.
Phone: 303-720-0017
hhertz@paragon28.com

Date Prepared: February 10, 2021

Common Name: Soft Tissue Fixation Device

Classification: 21 CFR 888.3040

Class: II

Product Code: MBI

Predicate Device:
The TenoTac® Soft Tissue Fixation System (K182898) serves as the primary predicate device.

Reference Device:
The Zimmer Biomet (formerly Biomet Sports Medicine) JuggerKnot™ Soft Anchors (K110145) serve as a reference device.

Indications for Use:
The TenoTac® Soft Tissue Fixation System is intended to be used for soft tissue to bone fixation.

Specific indications for the TenoTac® include:

> Foot & Ankle: Medial/lateral repair and reconstruction, mid and forefoot repair, hallux valgus repair, hallux malleus repair and reconstruction, metatarsal ligament/tendon repair and reconstruction including plantar plate attenuation and tear, and the correction of hammer toe, claw toe, mallet toe, crossover toe, floating toe, and any other lesser toe deformities, correction of metatarsophalangeal joint instability due to shortening from interphalangeal fusion, correction of metatarsophalangeal joint instability due to shortening from Weil osteotomy, Achilles tendon repair.

Hand & Wrist: Collateral ligament repair, Scapholunate ligament reconstruction, tendon transfers in phalanx, Volar plate reconstruction.

Device Description:
The TenoTac® Soft Tissue Fixation System is manufactured from titanium alloy (Ti-6Al4V ELI per ASTM F136) and is comprised of specialized threaded tacks/male implants and associated threaded sleeves/female implants for attaching soft tissue to bone. The tacks and sleeves are available in various sizes and lengths to accommodate different bone sizes.

Substantial Equivalence:
The TenoTac Soft Tissue Fixation system is intended for soft tissue to bone fixation. Compared to the predicate TenoTac device, the subject device is a two-piece titanium tack and sleeve construct inserted on two ends of a bone canal. There are no differences between these devices. Compared to the JuggerKnot device, the subject device achieves the same intended effect by fixing soft tissue through a bone canal. Differences include the shape of the anchors and the material of the anchors. All indications for the subject device are within the indications of the predicate devices. In addition, the subject device possesses the same technological characteristics as the predicate device, including performance, basic design, material, manufacturing, and sizes. Therefore, the TenoTac Soft Tissue Fixation System is substantially equivalent to the predicate devices with respect to indications, design, function, and performance.

Performance Testing:
Neither clinical or non-clinical testing were necessary to support substantial equivalence of the subject device.

Conclusion:

The TenoTac Soft Tissue Fixation System possesses the same intended use and technological characteristics as the predicate and reference devices. Therefore, the TenoTac Soft Tissue Fixation System is substantially equivalent for its intended use.