January 14, 2019

Paragon 28, Inc.
Eric Lintula
Director of Regulatory Affairs
4B Inverness Court E, Suite 280
Englewood, Colorado 80112

Re: K182898
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: October 10, 2018
Received: October 16, 2018

Dear Mr. Lintula:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K182898

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® include:
· Foot & Ankle: Medial/lateral repair and reconstruction, mid and forefoot repair, hallux valgus repair, metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

Device Trade Name:	TenoTac® Soft Tissue Fixation System
510(k) Number:	K182898
Manufacturer:	Paragon 28, Inc. 4B Inverness Ct, E STE 280 Englewood, CO 80112
Contact:	Eric Lintula Phone: 888-728-1888 elintula@paragon28.com
Date Prepared:	October 10th, 2018
Common Name:	Soft Tissue Fixation Device
Classification:	21 CFR 888.3040
Class:	II
Product Code:	MBI

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, metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair

Device Description:
The TenoTac® Soft Tissue Fixation System is manufactured from titanium alloy (Ti-6Al-4V 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.

Predicate Devices:
The Zimmer Biomet (formerly Biomet Sports Medicine) JuggerKnot™ Soft Anchors device (K110145) serves as the predicate device.

Predicate Comparison:

Indications

The subject and predicate devices are intended to be used for soft tissue to bone fixation. Both devices are indicated for use in the foot and ankle. All indications for the subject device are covered within the indications of the predicate.

Technological Characteristics

Both the subject and predicate constructs are designed to achieve temporary fixation of soft tissue to bone. In the case of the TenoTac®, the device goes through the near cortex and engages the far cortex to provide tension and compress the soft tissue and bone. In the case of the predicate device, the device is passed through the bone, and suture provides tension and compresses the soft tissue to the bone. The mechanical testing demonstrates that TenoTac® device is substantially equivalent to the predicate, and introduces no new issues of safety or effectiveness.

Nonclinical Testing

All necessary testing has been performed on representative TenoTac® Soft Tissue Fixation System devices 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 pull apart and static axial pullout testing in bone analog material. Bacterial endotoxin testing using the kinetic turbidimetric method was used for pyrogenicity testing to ensure an endotoxin limit of 20EU/Device. Clinical data are not needed to support the safety and effectiveness of the subject device.

Conclusion

Side-by-side performance testing demonstrates the substantial equivalence of the TenoTac® Soft Tissue Fixation System to the JuggerKnot™ Soft Anchors. The TenoTac® Soft Tissue Fixation System is substantially equivalent to the JuggerKnot™ Soft Anchors (K110145) with respect to its indications for use, design, and function.