March 1, 2019

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

Re: K183690
Trade/Device Name: Tenodesis 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: December 21, 2018
Received: December 31, 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,

Laurence D. Coyne -S

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)*
K183690

Device Name
Tenodesis Screw System

Indications for Use *(Describe)*
The Tenodesis 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
• 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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*"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."*

**510(k) Summary**

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| **Date:** | December 21st, 2018 |
| **510(k) Number:** | K183690 |
| **Sponsor:** | Paragon 28, Inc.<br>4B Inverness Ct. E., STE 280<br>Englewood, Colorado 80112<br>Phone: (888) 728-1888<br>Fax: (888) 728-1220 |
| **Sponsor contact:** | Eric Lintula, Director of Regulatory Affairs |
| **Trade Name:** | Tenodesis Screw System |
| **Regulatory Class:** | Class II |
| **Regulation, Product Code, Classification, and Common Name:** | 888.3040, MBI, Fastener, Fixation, Nondegradable, Soft Tissue |
| **Device Descriptions:** | The Tenodesis Screw System is composed of a screw manufactured from polyetheretherketone (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. |
| **Indications for Use:** | The Tenodesis 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:<br><u>Shoulder:</u><br>• Rotator Cuff Repairs<br>• Bankart Repair<br>• SLAP Lesion Repair<br>• Biceps Tenodesis<br>• Acromio-Clavicular Separation Repair<br>• Deltoid Repair<br>• Capsular Shift or Capsulolabral Reconstruction.<br><u>Foot/Ankle:</u><br>• Lateral Stabilization<br>• Medial Stabilization<br>• Achilles Tendon Repair<br>• Hallux Valgus Reconstruction<br>• Midfoot Reconstruction<br>• Metatarsal Ligament Repair<br>• Flexor Hallucis Longus Transfer for Achilles Tendon Reconstruction, and<br>• Flexor Digitorum Longus Transfer for Posterior Tibial Tendon Reconstruction.<br><u>Knee:</u> |

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| | • Anterior Cruciate Ligament Repair<br>• Medial Collateral Ligament Repair<br>• Lateral Collateral Ligament Repair<br>• Patellar Tendon Repair<br>• Posterior Oblique Ligament Repair<br>• Illiotibial Band Tenodesis<br><u>Elbow:</u><br>• Biceps Tendon Reattachment<br>• Ulnar or Radial Collateral Ligament Reconstruction<br><u>Hand/Wrist:</u><br>• Scapholunate Ligament Reconstruction<br>• Ulnar Collateral Ligament Reconstruction<br>• Radial Collateral Ligament Reconstruction<br>• Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)<br>• Carpal Ligament Reconstructions and repairs<br>• Ligament Reconstruction and Tendon Interposition. |
| **Materials:** | The Tenodesis Screw System implants are made from PEEK per ASTM F2026. The instrumentation is primarily manufactured from medical grades of stainless steel. |
| **Primary Predicate:** | K051726, Arthrex Tenodesis Screw Family |
| **Comparison to Predicate Indications:** | The subject Tenodesis Screw System and Arthrex Tenodesis Screw Family devices are intended to be used for soft tissue reattachment. All indications for the subject device are within the indications of the predicate devices. |
| **Comparison to Predicate Technological Characteristics:** | The subject Tenodesis Screw System components possess the same technological characteristics as the respective predicate devices. These include:<br>• performance,<br>• basic design,<br>• material, manufacturing and<br>• sizes (dimensions are comparable to those offered by the predicate systems).<br>Differences between the Tenodesis Screw System and Arthrex Tenodesis Screw Family implants were shown not to raise new questions of safety and effectiveness. Therefore, the fundamental scientific technology of the subject Tenodesis Screw System components is similar to previously cleared devices. |
| **Performance Data:** | All necessary testing has been performed on representative Tenodesis Screw System components to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended. All testing was performed on finished devices. |

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| | 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.<br>A Bacterial Endotoxin Test has been conducted on the subject device and it meets the specified 20 EU/Device limit. This is the recommended limit for devices that do not contact the cerebrospinal fluid. |
| **Conclusion:** | Performance testing demonstrates the substantial equivalence of the Tenodesis Screw System to the Arthrex Tenodesis Screw Family. Therefore, the Tenodesis Screw System is substantially equivalent to the predicate devices with respect to their indications for use, technical characteristics, and function. |