510(k) Summary or 510(k) Statement

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Name of Device	Arthrex 2.5 mm Tenodesis Screw
Common Name	Screw, fixation, bone Fastener, Fixation, Nondegradable, Soft Tissue
Product Code	HWC; MBI
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K063479: Arthrex 2.5 mm PushLock K172612: Arthrex FiberTak DX (Reference)
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex 2.5 mm Tenodesis Screw.
Device Description	The Arthrex 2.5 mm Tenodesis Screw is a fully threaded, cannulated screw with a rounded head. The screw will be offered in a 2.5 mm diameter and 6 mm length. The screw is manufactured from Polyetheretherketone (PEEK). The screw is sold as sterile, single-use.
Indications for Use	The Arthrex 2.5 mm Tenodesis Screw is intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, and shoulder. Specific indications are listed below: *Elbow:* Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction *Shoulder:* Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction *Hand/Wrist:* Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers *Foot/Ankle:* Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction *Knee:* Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Technological Comparison	The Arthrex 2.5 mm Tenodesis Screw is substantially equivalent to the predicate devices in which the basic design features, intended use, indications for use, material, biocompatibility, method of sterilization, packaging, and shelf-life are

	identical. The Arthrex 2.5 mm Tenodesis Screw is a line extension to the predicate devices, which include minor dimensional modifications with no change to intended use or function. Any differences between the Arthrex 2.5 mm Tenodesis Screw and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Performance Data	Pull-out and failure torque/insertion torque testing were conducted to demonstrate that the Arthrex 2.5 mm Tenodesis Screw performs statistically equivalent to the predicate device cleared under K063479. The Arthrex 2.5 mm Tenodesis Screw is sterilized by ethylene oxide (EO). The sterility assurance level (SAL) is 10^{-6}. This is identical to the predicate devices cleared under K063479 and K172612. The shelf life of the Arthrex 2.5 mm Tenodesis Screw is five (5) years for the Polyetheretherketone (PEEK) material, which is identical to the predicate devices cleared under K063479 and K172612. Bacterial Endotoxins Test (BET) was performed on the Arthrex 2.5 mm Tenodesis Screw utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820. The testing conducted demonstrates that the Arthrex 2.5 mm Tenodesis Screw meets pyrogen limit specifications. Cytotoxicity, Sensitization, Irritaion, Genotoxicity, Systemic Toxicity, Subchronic/Subacute Toxicity, Implantation and Material Characterization testing was conducted on the Arthrex 2.5 mm Tenodesis Screw in accordance with ISO 10993-1:2018.
Conclusion	The Arthrex 2.5 mm Tenodesis Screw is substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate devices are considered minor and do not raise different questions of safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the Arthrex 2.5 mm Tenodesis Screw is substantially equivalent to the currently marketed predicate device.