510(k) Summary

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Name of Device	SutureLoc™ Implant
Common Name	Fastener, Fixation, Nondegradable, Soft Tissue
Product Code	MBI
Classification Name	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.
Regulatory Class	II
Predicate Device	K173845 Arthrex SwiveLock® Anchors
Reference Device	K203268 Arthrex Knotless FiberTak®
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the new Arthrex SutureLoc™ Implant.
Device Description	The SutureLoc™ Implant is a suture construct comprised of a polyester sheath with multiple sutures assembled through the sheath.
Indications for Use	The Arthrex SutureLoc™ Implant is intended to be used for suture (soft-tissue) fixation to bone in the knee for meniscal root repair.
Summary of Technological Characteristics	The proposed device has the same intended use and fundamental technology as the predicate and reference devices. The subject device is comprised of multiple sutures manufactured using the same materials as the Knotless FiberTak® (K203268) device. The primary differences include the stitching suture and use of an accessory device to pull the anchor into the bone.
Performance Data	Ultimate load testing and cyclic displacement was performed on the subject device to demonstrate that the differences do not negatively impact mechanical strength. Bacterial endotoxin per USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications. Packaging testing was conducted to demonstrate shelf-life and confirm the packaging design provides a protective sterile barrier and protects the integrity of the products post sterilization during shipping and handling.
Conclusion	The Arthrex SutureLoc™ Implant is substantially equivalent to the predicate devices in which the basic design features, intended use and surgical technique are the same. Any differences between the subject device and the predicate devices do not raised questions concerning safety and effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate devices.