510(k) Summary *Date Prepared*	October 1st, 2019
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Name of Device	*Arthrex Double Syringe (ACP) Kit*
Common Name	Platelet and Plasma Separator For Bone Graft Handling
Product Code	ORG
Classification Name	21 CFR 864.9245
Regulatory Class	II
Predicate Device	BK070069 – Arthrex Double Syringe (ACP, Autologous Conditioned Plasma) System
Purpose of Submission	This Special 510(k) Premarket Notification is submitted to add a line extension of the Arthrex Double Syringe System previously cleared under BK070069.
Device Description	The new Arthrex Double Syringe (ACP) System consists of the ACP Double syringe cleared under BK070069 packaged with various instrumentation and ACD-A (Anticoagulant Citrate Dextrose Solution A).
Indications for Use	The Arthrex Double Syringe (ACP) Kit is indicated for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.
Performance Data	A packaging validation study was conducted to ensure the packaging design and material are capable of maintaining packaging sterile integrity and protecting the components within them from damage. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that The device meets pyrogen limit specifications.
Conclusion	The proposed Arthrex Double Syringe (ACP) System is substantially equivalent to the predicate device which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary

	of data submitted, Arthrex Inc. has determined that the Arthrex Double Syringe (ACP) System is substantially equivalent to the currently marketed predicate device.