510(k) Summary of Safety and Effectiveness

Manufacturer/Sponsor	Arthrex, Inc.1370 Creekside Boulevard Naples, Florida 34108-1945
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Trade Name	Arthrex Double Syringe (ACP, Autologous Conditioned Plasma) System
Common Name	Piston Syringe
Product Code	**FMF :** Piston Syringe **JCQ :** General purpose laboratory equipment/specific medical labeled or promoted for a specific medical use
Predicate Devices	**BK020051:** Cascade Medical Fibrinet, Autologous Platelet System **BK050055:** GenesisCS Component Concentrating System
Device Description and Intended Use	The ***Double Syringe (ACP) System*** is a specially designed 10 mL outer syringe. Within this outer syringe a commercially available 5 mL syringe is connected. The 10mL outer syringe holds the blood while it is centrifuged in benchtop centrifuge (Rotofix 32A). During the extracorporeal blood processing 1 mL of Anticoagulant Citrate Dextrose Solution (ACD-A) is used to prevent clotting. The special design of the Double Syringe allows transferring the supernatant from the 10 mL outer syringe into the 5 mL syringe under aseptic conditions. The ***Double Syringe (ACP) System*** is used to facilitate the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient's point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.
Substantial Equivalence Summary	Arthrex has determined that the Arthrex ***Double Syringe (ACP) System*** is substantially equivalent to the predicate devices where basic features and intended uses are the same. Any design differences between the Arthrex Double Syringe (ACP) System and the predicate devices (**KBK020051, BK050055)** are considered minor and do not raise any questions concerning safety and effectiveness. Any differences have been found to have no apparent effect on the performance, function, or intended use of the device.