

510(k) Summary

Date Prepared	February 2, 2018
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	David L Rogers Project Manager, Regulatory Affairs 1-239-643-5553, ext. 71924 david.rogers@arthrex.com
Name of Device	Arthrex Angel System Kits
Common Name	Automated blood cell separator
Product Code	ORG
Classification Name	21 CFR 864.9245
Regulatory Class	II
Predicate Device	BK110046: Arthrex Concentrated Platelet Rich Plasma (cPRP) System
Purpose of Submission	This Special 510(k) premarket notification is submitted to add a line extension of Arthrex Angel System Kits to the Arthrex Angel Concentrated Platelet Rich Plasma (cPRP) System cleared under predicate BK110046.
Device Description	The Arthrex Angel System Kits consist of the Angel cPRP Processing Kit cleared under BK110046 packaged with various instrumentation and ACD-A (Anticoagulant Citrate Dextrose Solution A).
Indications for Use	The Arthrex Angel System Kits are to be used in the clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of whole blood or a small mixture of blood and bone marrow. The platelet rich plasma can be mixed with autograft and/or allograft bone prior to application to an orthopedic site.
Performance Data	<p>A packaging validation study was conducted to ensure that the packaging design and material are capable of maintaining packaging and sterile integrity and protecting the components within them from damage.</p> <p>Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.</p>
Conclusion	<p>Arthrex Angel System Kits is substantially equivalent to the predicate device in 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.</p> <p>Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the Arthrex Angel System Kits are substantially equivalent to the currently marketed predicate device.</p>