510(k) Summary

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Name of Device	*Thrombinator™ System for use with the Arthrex Angel concentrated Platelet Rich Plasma (cPRP) System*
Common Name	Platelet and Plasma Separator for Bone Graft Handling
Product Code	ORG
Classification Name	21 CFR 864.9245: Automated blood cell separator
Regulatory Class	II
Predicate Device	BK110040 (Primary Predicate): Clotalyst Kit with GPS® III Separator BK080004: Clotalyst and GPS III® Mini Platelet Concentrate Separation Kit with ACD-A , Clotalyst and GPS III Platelet Concentrate Separation Kit with ACD-A
Purpose of Submission	This Traditional 510(k) Premarket Notification is submitted to obtain FDA clearance for the *Thrombinator System for use with the Arthrex Angel concentrated Platelet Rich Plasma (cPRP) System*.
Device Description	The *Thrombinator System for use with the Arthrex Angel concentrated Platelet Rich Plasma (cPRP) System* includes a sterile, single-use device and a separate filter that aid in the preparation of autologous thrombin serum. Additional equipment used for blood draw and processing is not included.
Indications for Use	The *Arthrex Angel concentrated Platelet Rich Plasma (cPRP) System* is designed 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. The *Thrombinator System for use with the Arthrex Angel concentrated Platelet Rich Plasma (cPRP) System* is designed for the preparation of autologous serum from anticoagulated peripheral blood or platelet poor plasma that is to be mixed with the PRP and autograft or allograft bone prior to application to a bony defect for improving handling characteristics.
Performance Data	To demonstrate product performance, Arthrex has conducted clot time, thrombin concentration, bone graft hardness testing and compared the results to the predicate device. The *Thrombinator System for use with the Arthrex Angel concentrated Platelet Rich Plasma (cPRP) System* passed all performance testing criteria. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
Conclusion	The *Thrombinator System for use with the Arthrex Angel concentrated Platelet Rich Plasma (cPRP) System* is substantially equivalent to the predicate device in which the basic design features and intended uses are the same.

	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 predicate device.