510(k) Summary

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Trade Name	Arthrex Thrombinator 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
Primary Predicate Device	BK180299 – Arthrex Thrombinator System
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex Thrombinator System cleared via K180299 to include the addition of a third Arthrex PRP System, Arthrex ACP Max™ Platelet-Rich Plasma (PRP) System cleared via BK210655, to the Indication for Use. The proposed addition of the Arthrex ACP Max™ PRP System for use with the Arthrex Thrombinator System is to allow for a third Arthrex PRP System source.
Device Description	The Arthrex Thrombinator System includes a sterile, single-use device (i.e., Thrombinator tube construct) and a separate filter that aid in the preparation of autologous thrombin serum. Additional equipment used for blood draw and processing is available and sold separately and to be supplied by the end-user in order to operate the device as intended.
Indications for Use	The Thrombinator System for use with Arthrex PRP Systems (Arthrex Angel concentrated Platelet Rich Plasma cPRP System or Arthrex Double Syringe (ACP) System or Arthrex ACP Max™ Platelet-Rich Plasma (PRP) System) is designed for the preparation of autologous

	serum from anticoagulated or non-anticoagulated peripheral blood, platelet poor plasma, or platelet rich plasma (PRP) that is to be mixed with PRP and autograft or allograft bone prior to application to a bony defect for improving handling characteristics.
Performance Data	Performance testing, inclusive of thrombin activity and bone graft cohesive strength, was performed to demonstrate that the Arthrex Thrombinator System is substantially equivalent to the predicate device (BK180299).
Technological Comparison	The Arthrex Thrombinator System is substantially equivalent to the predicate device cleared under BK180299 in which the intended use, device material, technological characteristics, fundamental scientific technology, sterility, and shelf-life is identical. The Arthrex Thrombinator System will include the addition of a third Arthrex PRP System, Arthrex ACP Max™ Platelet-Rich Plasma (PRP) System cleared via BK210655 to the indication for use. Any differences between the Arthrex Thrombinator System and the predicate device are considered minor and do not raise new or different questions concerning safety or effectiveness.
Conclusion	The Arthrex Thrombinator System is substantially equivalent to the predicate device in which the basic design features and intended use are the same. Any differences between the proposed Arthrex Thrombinator System and the predicate device are considered minor and do not result in new or different questions of safety or effectiveness. Based on the intended use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that proposed device is substantially equivalent to the currently marketed device.