510(k) Summary

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Name of Device	*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
Predicate Device	BK170144 – Thrombinator System for use with the Arthrex Angel concentrated Platelet Rich Plasma (PRP) System
Purpose of Submission	This Traditional 510(k) Premarket Notification is submitted to incorporate the use of PRP as autologous fluid in the formation of autologous serum and to request incorporation of Arthrex PRP systems in the indications for use. This 510K is also submitted to extend the shelf life extension of the product from 2 to 5 years.
Device Description	The *Arthrex Thrombinator System* for 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 available and sold separately.
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) 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	An analysis of coagulation and bone graft cohesive strength was performed to demonstrate that the Arthrex Thrombinator exhibits similar or better thrombin activity when compared with the predicate.
Conclusion	The proposed T*hrombinator System* is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. The autologous serum can be prepared from multiple autologous fluid sources and was able to improve bone graft handling when used with Arthrex PRP systems which is equivalent to the originally cleared Thrombinator under K170144. 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 proposed device is substantially equivalent to the currently marketed predicate device.