510(k) Summary

Date Prepared	August 22, 2022
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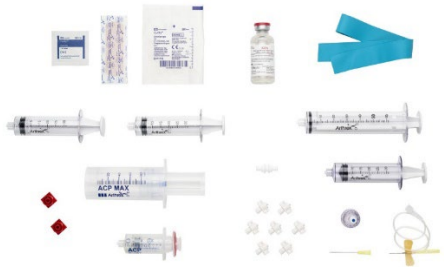
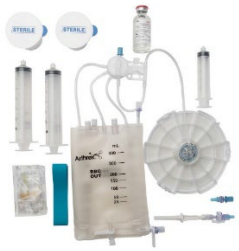
Name of Device	Arthrex Autologous Conditioned Plasma (ACP) MAX™ PRP System
Common Name	Automated blood cell separator
Product Code	ORG
Classification Name	21 CFR 864.9245 Platelet And Plasma Separator For Bone Graft Handling
Regulatory Class	II
Predicate Devices	BK180180- Arthrex Angel PRP System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Autologous Conditioned Plasma (ACP) MAX™ PRP System
Device Description	The Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system consists of a large barrel syringe, 30mL syringes, and the Arthrex Autologous Conditioned Plasma (ACP)® double-syringe system. The Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system was specifically designed to function with the Arthrex ACP double-syringe system where platelet rich plasma (PRP) is produced. To prepare the PRP, a sample of the patient's blood can be combined with Anticoagulant Citrate Dextrose A Solution (ACD-A) to prevent coagulation during processing. The systems are connected via a Luer lock connector. A threaded screw cap connected to the luer tip of the outer syringe can be removed prior to use. The Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system is comprised of two packaging sub-components: 1) Inner Blister Tray and 2) Outer Blister Tray. Within the Inner Blister Tray, a specially designed large barrel syringe (ACP Max device) which holds up to 90mL of fluid, red luer caps, (2) 30mL syringes, and an Arthrex ACP® double-syringe that was previously cleared in BK190406 are included. The Outer Blister Tray is comprised of FDA cleared Original Equipment Manufacturer (OEM) components and ACD-A. Arthrex receives the OEM component and ACD-A and places them in the Outer Blister Tray without further manufacturing, processing, or re-labeling. The OEMs and ACD-A provided in the Outer Blister Tray have been previously FDA cleared in BK180180 for the Arthrex Angel System Kit or BK190406 for the Arthrex Double Syringe (ACP) kit The proposed Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system was designed to be used with benchtop centrifuges with swing-out rotors that securely accommodate the device (e.g., Hettich Rotofix 32 A benchtop centrifuge or Drucker Horizon 24 Flex).

Indications for Use	The Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system is indicated to be used intraoperatively at the point of care for the safe and rapid preparation of autologous platelet concentrate platelet rich plasma (PRP) from a small sample of peripheral blood or a small sample of a mixture of peripheral blood and bone marrow. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

Technological Comparison:

Device Similarities & Differences	**Arthrex Autologous Conditioned Plasma (ACP) MAX™ PRP System ~ *This submission* ~**	**Arthrex Angel PRP System (BK180180) ~Predicate Device ~**	**Equivalency**
Device(s)			
Product Code	ORG	ORG	Equivalent to predicate BK180180
21 CFR	864.9245	864.9245	Equivalent to predicate BK180180
Regulation Name	Platelet and plasma separator for bone graft handling	Platelet and plasma separator for bone graft handling	Equivalent to predicate BK180180
Intended Use	The Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP System is indicated to be used intraoperatively at the point of care for the safe and rapid preparation of autologous platelet concentrate (platelet rich plasma) from a small sample of peripheral blood or a small sample of a mixture of peripheral blood and bone marrow. The platelet rich plasma is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.	The Arthrex Angel System Kits are to be used intraoperatively at the point of care for the safe and rapid preparation of autologous platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of peripheral blood or a small sample of a mixture of peripheral blood and bone marrow. The platelet poor plasma and platelet rich plasma are mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.	The proposed ACP Max™ PRP System: The platelet rich plasma is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics. Predicate BK180180: The platelet poor plasma and platelet rich plasma are mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.
Principals of Operation	Separation of liquids based on density	Separation of liquids based on density	Equivalent to predicate BK180180
Blood component separation method	Centrifuge with two stage spin	Centrifuge with two stage spin	Equivalent to predicate BK180180
Processing Volume	30mL minimum 90mL maximum	Minimum 40mL; Cumulative maximum 180mL processed in 1 to 3 cycles.	Proposed device can accommodate a volume from 30-90mL. BK180180 can accommodate 40mL to 180mL Minor difference in blood volumes
Material – Device (not including OEM components)	Polypropylene, Polycarbonate, Silicone, Isoprene Rubber, TPE, Polyisoprene	Polyethylene, PVC, stainless steel, polycarbonate, polyurethane	Proposed device: Polypropylene, Polycarbonate, Silicone, Isoprene Rubber, TPE, Polyisoprene BK180180: Polyethylene, PVC, stainless steel, polycarbonate, polyurethane

Device Similarities & Differences	**Arthrex Autologous Conditioned Plasma (ACP) MAX™ PRP System ~ *This submission* ~**	**Arthrex Angel PRP System (BK180180) ~Predicate Device ~**	**Equivalency**
			Minor difference in materials
Packaging	Outer PETG tray with OEM components Inner PETG tray sealed with Tyvek lid	PETG blister tray with sterile pouch and OEM components	Proposed device: Outer PETG tray with OEM components Inner PETG tray sealed with Tyvek lid BK180180: PETG blister tray with sterile pouch and OEM components Minor differences in packaging configurations
Sterility	Ethylene Oxide/ Gamma Irradiation	Ethylene Oxide/ Gamma Irradiation	Equivalent to predicate BK180180
Shelf life	2 years	3 years	Predicate BK180180 shelf life is 3 years and proposed device shelf life is 2 years
Single Use	Yes	Yes	Equivalent to predicate BK180180

Performance Data

The following non-clinical performance testing was submitted in support of a determination of substantial equivalence between the subject and predicate device.

Bench Testing – In vitro Performance Testing:

Arthrex Inc conducted an Equivalency Testing which compared the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system at a minimum (30mL) and maximum (90mL) input volumes to Angel (90mL) device. The Equivalency Testing evaluated the Complete Blood Count (CBC), pH, platelet aggregation, hypotonic stress recovery, and resting/activated p-selectin expression at 0 and 4 hours post collection. Testing also confirmed the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system has a pH of at least (b) (4) with at least 50% platelet recovery. The Equivalency testing also utilized a 20% margin to evaluate product stability and equivalence to predicate device.

Bone Graft Cohesion Testing was performed to evaluate the subject and predicate PRP hydrated bone graft handling characteristics including the ability of the graft to retain the shape of the syringe mold, to have improved handling properties (i.e., graft can be picked up), and quantitative graft hardness using a durometer. Paired Equivalence Testing was utilized to evaluate the two-sided 90% confidence interval for the ratio of the subject device to predicate device is between 0.80 and 1.25. The results demonstrated that the PRP produced in the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system was substantially equivalent to the predicate device, Angel cPRP System, in its ability to improve bone graft cohesion.

Verification Testing was performed for the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system per internal design requirements. Verification Test results demonstrated that the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system is functioning as intended per internal design requirements.

Mechanical Testing was performed for Verification of the ACP Max Syringes. Test results indicated that the acceptance criteria for the ACP Max Syringes were met.

Biocompatibility Testing:
The biocompatibility evaluation of the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system was conducted in accordance with the FDA Guidance document, "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process," September 4th, 2020. Biocompatibility for the subject device, Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system is substantially equivalent to the predicate device.

Sterility Testing:
The Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system is validated and meets the requirements outlined in ISO 11135:2014, "Sterilization of health care products – Ethylene Oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices". The ethylene oxide cycle was validated to a Sterility Assurance Level of 10^{-6}. Product Residuals are tested after sterilization and aeration for (b) (4) at a temperature of (b) (4) to have (b) (4) and (b) (4) The ACP Max PRP System meets the residual limits according to predetermined acceptance criteria.

The White Luer Caps provided in the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system are validated and meet the requirements outlined in ISO 11137-1, "Sterilization of Health Care Products. Radiation – Requirements for development, validation, and routine control of sterilization process for medical devices," and ISO 11137-2, "Sterilization of Health Care Products. Radiation – Establishing the Sterilization Dose." The gamma radiation cycle was validated to a Sterility Assurance Level of 10^{-6}. The White Luer Caps for the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system meet the sterilization limits according to predetermined acceptance criteria.

Stability/Shelf Life Testing:
The shelf life of the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system has been determined to be 2-years. The Original Equipment Manufacturer (OEM) for the components provided in the Outer Tray are purchased as manufactured by the legal manufacturer and have their own shelf-life data. These components have been cleared for use under their respective regulatory submissions as described in Section 13 of this 510(k) submission. The overall expiration date of the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system is determined by the earliest expiration date of all the components.

Functional Testing was performed after 2-year accelerated aging for the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system per internal design requirements. Test results demonstrated that the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system met its design requirements for a shelf-life stability of 2-years.

Animal Testing:
No animal testing was performed.

	Clinical Testing: No clinical testing was performed.
Conclusion	The Arthrex Autologous Conditioned Plasma (ACP) MAX™ PRP System 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 different questions concerning safety or effectiveness. The submitted mechanical and biological testing data demonstrates that the proposed device is substantially equivalent to that of the predicate device for the desired indications. 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.