510(k) Summary - BK200543

I. SUBMITTER

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II. DEVICE

Common Name:	Platelet and Plasma Separator For Bone Graft Handling
Device Name:	Ranfac Autologous Platelet Separator
Regulation Description	Automated blood cell separator
Review Panel:	Hematology
Product Code:	ORG
Regulation Number:	21 CFR 846.9245
Device Class:	II

III. PREDICATE DEVICES

The legally marketed primary predicate device to which the Ranfac Autologous Platelet Separator (APS) device is substantially equivalent is the Arteriocyte Magellan Autologous Platelet Separator, which was subject of BK030040, cleared September 3, 2003. Although, the Arteriocyte Magellan device was classified before product code ORG was established and has a slightly different indication for use statement compared with the Ranfac APS review of BK030040 supports that the Arterioctye Magellan device is similar in intended use (separation of autologous platelets for improving bone graft handling) and principle of operation (separation via centrifugation) as the Ranfac APS. Additionally, the Emcyte PurePRP Supraphysiologic Concentrating System for platelet rich plasma (Emcyte Corporation BK190317, cleared February 12, 2020) is cited as a secondary predicate due to similarities in autologous blood processing parameters; i.e., dual spin process requiring transfer of platelet and plasma to a second chamber for platelet separation.

IV. DEVICE DESCRIPTION

The Ranfac APS is a single use procedure pack consisting of blood draw components, syringes, and a processing disposable (separator). Specifically, the following components are included in the pack: sterile processing disposables, sterile syringes, fluid transfer needles, ACD-A anticoagulant and blood draw accessories. With the Ranfac APS, separation of blood components relies on the principles of density gradient separation via centrifugation. The separator disposable is similar to a test tube and therefore will work in the Eppendorf swinging bucket centrifuge that is of an appropriate size and can be programed to create an RPM of 3200; g-force of 1600 for 8 minutes. A nonsterile reusable centrifuge bucket insert is provided separately that is designed to fit the Eppendorf centrifuge to keep the process disposable stable during centrifugation.

The system prepares 6mL of platelet rich plasma (PRP) from a small volume (60mL) of blood that is drawn at the time of treatment.

The materials of the system's components consist of medical grade polymers, elastomers, and stainless steel suitable for use in medical devices.

V. INDICATIONS FOR USE

The Ranfac Autologous Platelet Separator is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care for mixing with autograft and/or allograft bone to improve handling characteristics.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The fundamental scientific technology, materials of construction, processing methods and mechanism of operation are similar between the subject Ranfac APS and the predicate Arteriocyte device. Any differences between the subject and predicate device would not render the device "not substantially equivalent" or NSE, affect the safety or effectiveness, or raise different questions of safety and effectiveness. The following table outlines the comparison of the technological characteristics between the subject Ranfac APS and the primary predicate Arteriocyte Magellan Autologous Platelet Separator used for performance testing as well as the secondary predicate Emcyte PurePRP Supraphysiologic Concentrating System.

Characteristic	Ranfac APS (Subject Device)	Arteriocyte Magellan Autologous Platelet Separation System - Primary Predicate	Emcyte PurePRP Supraphysiologic Concentrating System - Secondary Predicate
510(k) Number	Not Assigned	BK030040	BK190317
Regulation	21 CFR 864.9245	21 CFR 880.5860	21 CFR 864.9245
Product Code	ORG	FMF	ORG
Intended Use	The Ranfac Autologous Platelet Separator is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care for mixing with autograft and/or allograft bone to improve handling characteristics.	The Magellan® Autologous Platelet Separator System is designed to be used in the clinical laboratory or intra-operatively at point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of blood. The plasma and concentrated platelets produced can be used for diagnostic tests. Additionally, the platelet rich plasma can be mixed with autograft and/or allograft bone prior to application to an orthopedic site as deemed necessary by the clinical use requirements.	The PurePRP Supraphysiologic Concentration System is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect to improve handling characteristics.
Components	Disposable concentrating device packaged with syringes, blood draw needles and blood draw accessories including ACD-A anticoagulant.	Disposable concentrating device packaged with syringes, blood draw needles and blood draw accessories including ACD-A anticoagulant	Disposable concentrating device packaged with syringes, aspiration needles, tubing and connectors and ACD-A anticoagulant.
Materials	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices
Device Technology			
Principle of Operation	Separation of blood based on density	Separation of blood based on density	Separation of blood based on density
Method of Processing	Centrifugation	Centrifugation	Centrifugation
Centrifuge Device	Non-proprietary general purpose centrifuge	Dedicated Autospin Centrifuge	Non-proprietary general purpose centrifuge

Characteristic	Ranfac APS (Subject Device)	Arteriocyte Magellan Autologous Platelet Separation System - Primary Predicate	Emcyte PurePRP Supraphysiologic Concentrating System - Secondary Predicate
Centrifugation Protocol	2 part spin with intermediate separation step [1600g for 2.0 minutes) followed by 1st extraction of platelet and plasma suspension transferred to second processing disposable, then 1600g for 6 minutes followed by extraction of platelet poor plasma.	1 part spin (programmed)	2 part spin with intermediate separation step [3800 RPM for 1.5 minutes) followed by 1st extraction of platelet and plasma suspension transferred to second chamber of processing disposable, then 3800 RPM for 5 minutes followed by second extraction of platelet poor plasma.
Sterile, Non-pyrogenic	Yes	Yes	Yes
How Sterilized	ETO	Unknown	ETO
Packaging	CSR Wrapped Tray placed in Tyvek Pouch	Tray and Pouch	Tray with Tyvek Lid

As can be seen from the table there are many similarities between the Ranfac APS and predicate Arteriocyte device. Although the Arteriocyte system includes a dedicated centrifuge system and the Ranfac APS can be used with a general purpose centrifuge, there are numerous other Autologous Platelet Separation systems that are designed for use with a general purpose centrifuge such as the Emcyte PurePRP Supraphysiologic Concentrating System and therefore this characteristic is not unique to the Ranfac APS. Further, both the Ranfac APS and secondary predicate Emcyte PurePRP System use a two-step centrifugation protocol requiring transfer of the platelet/plasma prepared from the 1st spin to a new chamber prior to the second spin for final preparation of PRP.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing:

Biocompatibility testing on the fluid contacting materials of the Ranfac APS device was conducted in accordance with ISO 10993-1 Biological Evaluation of Medical Devices – Part 1 and FDA Guidance. The Ranfac APS concentrating device is categorized as an externally

communicating device, with limited exposure (contact < 24 hours) with indirect blood contact. Testing included cytotoxicity (per ISO 10993-5), sensitization & intracutaneous reactivity (per ISO 10993-10), acute systemic toxicity (per ISO 10993-11), hemolysis testing (ASTM F756) and material-mediated pyrogenicity (ISO 10993-11).

Bench Testing:
A paired study evaluating PRP quality was conducted with the Ranfac APS and the predicate Arteriocyte Magellan Autologous Platelet Separator using blood collected from healthy human donors for processing into PRP. The following tests were performed: blood cell counts (platelets, erythrocyte cells, and leukocyte cells), platelet concentration factor, platelet yield, pH, platelet activation (resting and ADP stimulated), platelet aggregation, hypotonic stress response and bone graft retention testing. The results obtained demonstrate substantial equivalence of the Ranfac APS to the predicate device for all parameters evaluated.

Shelf-Life/Device Integrity
Testing was conducted to evaluate the functional and structural integrity of the Ranfac APS concentrator and its packaging following worse-case conditioning including 2 times sterilization and post-environmental, simulated shipping and aging. The results demonstrated that the devices/packaging structural and functional integrity remain intact following conditioning and the data support a 6-month shelf-life for the device.

Sterilization Validation / Pyrogenicity
The Ranfac APS is sterilized via a validated ethylene oxide (EO) process to a Sterility Assurance Level (SAL) of (b) (4) . Ethylene oxide residuals are within accepted limits. A bacterial endotoxin test (BET), specifically, the Limulus amebocyte lysate (LAL) test, is used to establish that the device endotoxin level will be (b) (4) endotoxin units (EU)/device.

Clinical Studies:
No clinical studies were conducted for this submission.

VIII. CONCLUSION

Performance testing and comparison of characteristics between the subject and predicate devices have demonstrated that the Ranfac APS is substantially equivalent to the predicate devices with regard to intended use, operation, function, and technological characteristics.