510(k) SUMMARY

Type of Submission: Traditional

Date of Summary: 01/09/2025

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Identification of the Device:

Proprietary/Trade name:	AHC Platelet Concentrate Separator
Model Number:	0628-25, 0628-10-4, 0628-15-4
Classification Product Code:	ORG
Regulation Number:	864.9245
Regulation Description:	Platelet And Plasma Separator For Bone Graft Handling
Review Panel:	Hematology
Device Class:	II

Identification of the Predicate Device:

Predicate Device Name:	RegenKit-BCT Family Kits
Model Number:	RegenKit-BCT-1, RegenKit-BCT-2, RegenKit-BCT-3, RegenKit-BCT-4
Manufacturer:	RegenLab SA
Classification Product Code:	ORG
Regulation number:	864.9245

Device Class:	II
510(k) Number:	BK110061

Identification of the Predicate Device II:

Predicate Device Name:	RegenKit-ATS-3, RegenKit-BCT-1 Plus, RegenKit-BCT-2 Plus
Model Number:	RegenKit-ATS-3, RegenKit-BCT-1 Plus, RegenKit-BCT-2 Plus
Manufacturer:	RegenLab SA
Classification Product Code:	ORG
Regulation number:	864.9245
Device Class:	II
510(k) Number:	BK120066

Intended Use of the Device

The AHC Platelet Concentrate Separator is designed to be used for preparation of autologous platelet rich plasma from a small sample of peripheral blood for mixing with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

Device Description

The AHC Platelet Concentrate Separator is a single-use, sterile concentrating device. It concentrates blood components and aids in separation of the blood components by density through the use of additional components (not supplied), including blood draw components, syringes and centrifuge.

The system prepares platelet rich plasma (PRP) from a small volume of blood that is drawn at the time of treatment. The materials of the concentrating device consist of medical-grade PET Tube, separator gel, anticoagulant: Sodium Citrate Solution and rubber stopper.

The subject device is available in 3 models and the main differences between them are

the quantity and capacity of AHC PRP tube.

Non-clinical Testing

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

- **Sterilization Test**

  The sterilization method used on AHC Platelet Concentrate Separator is Gamma Irradiation sterilization. The sterilization process was validated by sterilization test.

  - Sterilization Validation of Gamma Irradiation
  - Gamma Sterilization Facility Validation Report

- **Shelf life test**

  The shelf life of AHC Platelet Concentrate Separator is claimed to be 2 years based on the 2-year accelerated study and the 2-year real time aging study is on-going.

  - Accelerated aging test
  - Real time aging test plan
  - Burst test
  - Creep test
  - Dye penetration test
  - Seal peel test

- **Biocompatibility test**

  A series of biocompatibility tests were conducted to assess the biocompatibility of AHC Platelet Concentrate Separator, 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 4, 2020.

  - In Vitro Cytotoxicity Test
  - Guinea Pig Skin Sensitization Study (Maximization Test)

- Rabbit Intracutaneous Irritation Study
- Acute Systemic Toxicity Study
- Pyrogen Study in Rabbits
- In vitro haemolysis study of AHC Platelet Concentrate Separator using rabbit blood (direct contact method)

- **Performance Test**

  A series of in vitro performance tests were conducted to verify the performance and equivalency of AHC Platelet Concentrate Separator and the predicate device.

  - Separation gel tests
  - Blood cell counts
  - Platelet recovery percentage
  - Platelet concentration factor
  - Platelet yield
  - pH measurement
  - P-selectin expression of platelet
  - Platelet aggregation
  - Hypotonic shock response (HSR)
  - Sterility test
  - Bone Graft cohesion

All the test results demonstrate AHC Platelet Concentrate Separator meets the requirements of its pre-defined acceptance criteria and intended use and is substantially equivalent to the predicate device.

Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

Substantial Equivalence Determination

The subject device has similar intended use, same technology/principle of operation, and similar claim of safety and performance as the predicate device.

Please refer to the following comparison table:

Comparison of Technological Characteristics			
Item	**Subject device**	**Predicate device**	**Substantial equivalence determination**
Manufacturer	Sunphoria Co.,Ltd	RegenLab SA	N/A
Trade Name	AHC Platelet Concentrate Separator	RegenKit-BCT Family Kits	N/A
Model	0628-25 0628-10-4 0628-15-4	RegenKit-BCT-1 RegenKit-BCT-2 RegenKit-BCT-3 RegenKit-BCT-4	N/A
510(k) No.	(to be assigned)	BK110061	N/A
Product Code	ORG	ORG	***Same***
Classification	Class II (21 CFR 864.9245)	Class II (21 CFR 864.9245)	***Same***
Intended Use	The AHC Platelet Concentrate Separator is designed to be used for preparation of autologous platelet rich plasma from a small sample of peripheral blood for mixing with	The RegenKit-BCT Family Kit is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient's point of	***Similar***

	autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.	care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics. The RegenKit-BCT Family Kits are for single use only.	
Separation principle	Gravity separation based on blood density	Gravity separation based on blood density	***Same***
Capacity	10, 15, 25 ml	15 ml	***Equivalent*** The subject device has models designed for various capacity, and this difference does not raise any new issue of substantial equivalence.
Required blood amount	7, 10, 20 ml	10 ml	
Extracted amount of PRP	3.5, 5, 6 ml	5-6 ml	
Used anticoagulant	USP 4% Sodium Citrate Solution	USP 4% Sodium citrate solution	***Same***
Method of processing	Centrifugation	Centrifugation	***Same***
Type of Centrifuge Used	Use a 45° fixed angle rotor centrifuge or a horizontal head swinging bucket centrifuge	Use a 45° fixed angle rotor centrifuge or a horizontal head swinging bucket centrifuge	***Same***
Centrifuge Condition	Centrifugal force: 740-820G Time: 10 mins	Centrifugal force: 1500G Time: 5 mins	***Equivalent*** The subject device has

			different centrifuge condition, and this difference does not raise any new issue of substantial equivalence.
Chambers	Single tube with plasma separated from red blood cells by cell selector gel	Single tube with plasma separated from red blood cells by cell selector gel	***Same***
Prescription Use	Yes	Yes	***Same***
Sterilization	Gamma Irradiation sterilization	Gamma Irradiation sterilization	***Same***
Sterile barrier	Packaged in sterile blister sealed with Tyvek	Packaged in sterile blister sealed with Tyvek	***Same***
Packaging	Blister	Blister	***Same***
Usage	For single use only	For single use only	***Same***
Self life	2 years	2 years	***Same***

Similarity and Difference

AHC Platelet Concentrate Separator is compared with “RegenKit-BCT Family Kits”. The subject device has similar intended use, same technology/mechanism of action, and similar safety and performance characteristics as the predicate device. Although there are some different specifications between these devices, the performance test was completed and demonstrated these differences don’t affect the safety and performance of the subject device. (referring to **Section 18**). Therefore, the differences between the subject device and the predicate device do not raise any new issue of substantial equivalence.

Conclusion

In conclusion, Sunphoria Co.,Ltd. believes that AHC Platelet Concentrate Separator maintains the same safety and effectiveness, and thus, is substantially equivalent to the predicate device.