510(k) Summary
BK210558

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Preparation Date:	July 23, 2021
Device Trade Name:	World PRP
Common Name:	Platelet and plasma separator for bone graft handling
Regulation Name:	Automated blood cell separator
Regulation Number:	21 CFR 864.9245 (Product Code: ORG)
Legally Marketed Predicate Devices:	RegenLab SA RegenKit-ATS-3, RegenKit-BCT-1 Plus, RegenKit- BCT-2 Plus
510(K) number:	BK120066
Regulatory Class:	Class II Prescription Use
Description of the World PRP:	The World PRP platelet concentrating system is a specially designed clear cylinder with a bottleneck design eliminating cell loss while easily being able to check both the quantity and the position of the buffy coat. The system allows for extraction from a single cycle of centrifugal separation yielding a high platelet concentration rate. The PRP kit is a closed system preventing airborne infections and is also compatible with multiple centrifugal separators on the market.
Intended use of World PRP:	For the rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft and allograft bone prior to application to a bony defect for improving handling characteristics.

Performance Testing:

The device biocompatibility testing was conducted in compliance with the following Standard(s):

- ISO-10993-5 : 2009, Biological Evaluation of Medical Devices, Part 5: Tests for in vitro cytoxicity
- ISO-10993-10 : 2010, Animal Intracutaneous (intradermal) reactivity Test
- ISO-10993-10 : 2010, Guinea Pig Maximization Test
- ISO-10993-11 : 2006, Acute Systemic Toxicity
- ISO-10993-11 : 2006, Information on material-mediated pyrogens
- USP 39, <151> Pyrogen Test
- ISO-10993-4 : 2017 Biological Evaluation of Medical Devices Part 4: Selection of tests for Interactions with Blood
- ASTM F756-17

A comparative study was conducted for the World PRP to show equivalence to the predicate device. This testing included a side-by-side comparison of the platelet concentrates to show equivalence in the following tests:

- Platelet Concentration Factor
- Platelet Yield
- pH
- Platelet activation
- Platelet Aggregation
- Hypotonic Stress Response
- White Blood Cell, Red Blood Cell, Hematocrit and Platelet counts
- Bone Graft Retention

Results of this study show the World PRP to be equivalent to the predicate device.

Results of Clinical Study:

A human clinical study was not required as the device is substantially equivalent to the predicate devices.

Technical Specifications / Indications for Use Comparison:

	Predicate device (BK120066)	510(K) Pending
Name	RegenKit-ATS-3, RegenKit-BCT-1 Plus, RegenKit-BCT-2 Plus	World PRP
Separation principle	Separation based on density of liquids	Separation based on density of liquids
Sterilization	Yes/ Gamma Sterilization	Yes/ Gamma Sterilization
Single Use	Yes	Yes
Shelf Life	3 years	3 years
Device Component	Blood Container	Blood Container
Required blood amount / container	8-10ml	23ml
Used Anticoagulant	Thrombin	ACD solution A
Required anticoagulant volume	2ml	2ml
Method of processing	Centrifugation	Centrifugation

Type of Centrifuge Used	Swing type	Swing type
Spin Time	5 minutes	3 minutes
Centrifugal Force (RCF)	1500 rcf	3000 rcf
Method of Extraction	Needle aspiration method	Extraction with a needleless Syringe
Extracted amount of PRP	5-6ml	6-7ml
Chambers	Single tube with plasma separated from red blood cells by cell selector gel	Both inlet(for blood infusion) and outlet(for PRP extraction) are separated to avoid and reduce risk of contaminations in the air.
Packaging	Blister	Pouch
Indication for use	For the rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft and allograft bone prior to application to a bony defect for improving handling characteristics.	For the rapid preparation of autologous platelet rich plasma (PRP) from a small sample of 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 for improving handling characteristics.
Component	Butterfly Needle Collection Holder BCT Tube Transfer Device Transfer Needles 5ml Syringe(s)	Tube

Conclusion: The World PRP intended use, indications for use and technical specifications are substantially equivalent to the RegenLab RegenKit-ATS-3, RegenKit-BCT-1 Plus, and RegenKit-BCT-2 Plus.