510(k) Summary

I. SUBMITTER

Date Prepared	2023-05-24
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II. DEVICE

Name of Device	Dr.PRP
Common Name	Platelet and Plasma Separator for Bone Graft Handling
Product Code	ORG
Regulation Number	21 CFR 864.9245
Classification Name	Automated Blood Cell Separator
Device Class	Class II
Review Panel	Hematology

III. PREDICATE DEVICE

GenesisCS Component Concentrating System, BK050055

IV. DEVICE DESCRIPTION

The Dr.PRP is provided as individually packaged sterile, single-use, disposable concentrating unit which is composed of medical grade polymer and elastomer. The concentrating unit has 20 ml of volume capacity and is designed to work with a swing rotor type general purpose centrifuge

V. INDICATIONS FOR USE

The Dr.PRP 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.

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 Dr.PRP and predicate. Both devices are provided as sterile concentrating unit (tube), designed to concentrate and aid in separation of blood by density through the

use of a centrifuge. Both devices include a single-use, disposable concentrating unit that is designed to accept a volume of blood, and then undergo centrifugal processing, in order to obtain platelet concentrate (PRP). Both devices have substantially same intended use. Dr.PRP is biocompatible and is composed of medical grade polymer and elastomer like its predicate. The table below summarizes the comparison of characteristics between the subject and predicate devices.

Charicteristic	**Primary Predicate device (GenesisCS Component Concentrating System, BK050055).**	**Subject device (Dr.PRP)**	**Comparison**
Intended Use	The GenesisCS Component Concentrating System 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 care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements	The Dr.PRP is designed to be used for the safe and rapid preparation of autologous platelet rich plasma 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 to improve handling characteristics	Similar –Both devices are designed to be used for the safe and rapid preparation of autologous platelet rich plasma from a small sample of blood at the patient's point of care.
Component	Disposable concentrating unit (tube) packaged with syringes, blood draw needle and blood draw accessories	Disposable concentrating unit (tube)	Similar – subject does not include higher risk accessories like needle. This difference does not raise any new issue of substantial equivalence
Material	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices	Medical grade polymer and elastomer suitable for use in medical devices	Similar – subject does not include higher risk accessories like needle. This difference does not raise any new issue of substantial equivalence
Principle of Operation	Separation of blood based on density	Separation of blood based on density	Identical
Method of Processing	Centrifugation	Centrifugation	Identical
Centrifuge Device	General purpose centrifuge	General purpose centrifuge	Identical
Usage	For single use only	For single use only	Identical
Sterile	Yes	Yes	Identical

VII. PERFORMANCE DATA

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

Bench Testing – In vitro Performance Testing

two-sided 90% confidence interval for the ratio of test device mean to predicate device mean.

a. Two-sided 90% confidence intervals for platelet function data at Time Point 0 hour.

Time Point 0 hour	pH		p-selectin (resting)		p-selectin (ADP)		HSR		Aggregation (collagen)	
	Subject	Predicate	Subject	Predicate	Subject	Predicate	Subject	Predicate	Subject	Predicate
Data (*n*=6)	7.3 7.2 7.3 7.2 7.3 7.2	6.9 6.8 6.8 6.8 6.8 6.8	11.0 10.8 8.8 10.7 9.1 8.9	10.9 7.9 11.9 9.0 8.8 9.9	50.8 52.5 53.1 54.2 49.2 51.5	51.9 54.3 53.3 51.2 48.4 49.4	91.6% 95.5% 94.4% 94.1% 93.3% 95.5%	95.6% 94.6% 93.4% 93.1% 96.3% 94.1%	67 78 47 49 86 33	57 80 59 68 48 41
Mean	7.25	6.82	9.88	9.73	51.9	51.4	94.1%	94.5%	60.0	58.8
Ratio	1.064		1.040		1.010		0.995		1.044	
S.D.	0.008		0.219		0.036		0.025		0.401	
90% C.I.	0.005		0.147		0.024		0.017		0.269	
two-sided 90% C.I. (0.8 ~1.25)	1.06 ~ 1.07		0.89 ~ 1.19		0.99 ~ 1.03		0.98 ~ 1.01		0.77 ~ 1.31	
	Substantial Equivalence		Substantial Equivalence		Substantial Equivalence		Substantial Equivalence		-	

b. Two-sided 90% confidence intervals for platelet function data at Time Point 4 hours.

Time Point 4 hours	pH		p-selectin (resting)		p-selectin (ADP)		HSR		Aggregation (collagen)	
	Subject	Predicate	Subject	Predicate	Subject	Predicate	Subject	Predicate	Subject	Predicate
Data (*n*=6)	7.3 7.2 7.3 7.2 7.3 7.2	6.9 6.8 6.8 6.8 6.8 6.8	28.5 26.3 26.1 31.1 26.9 28.6	26.6 29.3 25.7 24.2 25.5 26.6	78.1 78.8 80.5 77.4 78.5 77.8	77.5 79.5 78.3 77.6 76.8 78.5	96.2% 96.6% 96.3% 96.1% 95.4% 97.7%	94.9% 95.7% 94.5% 96.1% 95.5% 97.3%	64 64 48 58 65 52	59 58 74 64 64 54
Mean	7.25	6.82	27.9	26.3	78.5	78.0	96.4%	95.7%	58.5	62.2
Ratio	1.064		1.067		1.006		1.008		0.954	
S.D.	0.008		0.126		0.016		0.008		0.167	
90% C.I.	0.005		0.084		0.011		0.005		0.112	
two-sided 90% C.I.	1.06 ~ 1.07		0.98 ~ 1.15		1.00 ~ 1.02		1.00 ~ 1.01		0.84 ~ 1.07	

(0.8 ~1.25)	Substantial Equivalence	Substantial Equivalence	Substantial Equivalence	Substantial Equivalence	Substantial Equivalence

c. Two-sided 90% confidence intervals for cellular composition data at Time 0

Time Point 0 hour	**WBC**		**RBC**		**PLT**		**PLT Recovery**		**Concentration Factor**	
	Subject	Predicate	Subject	Predicate	Subject	Predicate	Subject	Predicate	Subject	Predicate
Data (*n*=20)	8.0	8.0	0.22	0.20	728	638	60.8%	53.7%	4.14	3.63
	7.4	7.4	0.22	0.20	666	654	68.0%	67.3%	4.63	4.54
	10.2	9.6	0.34	0.32	894	942	67.1%	71.2%	4.56	4.81
	9.6	9.2	0.14	0.14	1348	1254	82.3%	77.1%	5.59	5.20
	16.2	15.4	0.82	0.72	1002	992	70.5%	70.3%	4.79	4.75
	13.2	13.0	0.46	0.44	916	920	69.4%	70.3%	4.72	4.74
	8.0	7.8	0.22	0.20	782	786	67.3%	68.1%	4.57	4.60
	14.6	13.6	0.44	0.42	720	684	66.6%	63.7%	4.53	4.30
	12.0	11.2	0.58	0.54	1056	1010	70.9%	68.3%	4.82	4.61
	13.0	12.6	0.28	0.28	1204	1176	72.6%	71.4%	4.93	4.82
	13.2	13.2	0.44	0.46	976	944	73.2%	71.4%	4.98	4.82
	8.0	7.8	0.22	0.20	794	758	69.1%	66.4%	4.70	4.49
	14.6	14.0	0.44	0.42	726	704	66.7%	65.2%	4.54	4.40
	10.0	9.8	0.32	0.32	970	904	78.4%	73.6%	5.33	4.97
	10.0	9.2	0.16	0.16	1398	1278	77.9%	71.7%	5.30	4.84
	15.4	14.8	0.78	0.72	1010	1002	79.4%	79.4%	5.40	5.36
	12.8	12.0	0.32	0.26	1212	1136	74.0%	69.8%	5.03	4.71
	11.6	11.0	0.54	0.50	1012	986	74.0%	72.7%	5.03	4.91
	7.2	7.2	0.20	0.20	702	722	71.2%	73.8%	4.84	4.98
	7.8	7.4	0.20	0.20	652	608	57.8%	54.3%	3.93	3.66
Mean	11.14	10.71	0.37	0.35	938.4	904.9	70.9%	69.0%	4.82	4.66
Ratio	1.038		1.058		1.037		1.029		1.037	
S.D.	0.027		0.063		0.044		0.044		0.044	
90% C.I.	0.010		0.023		0.016		0.016		0.016	
two-sided 90% C.I.	1.028 ~ 1.048		1.035 ~ 1.082		1.020 ~ 1.053		1.013 ~ 1.045		1.020 ~ 1.053	
(0.8 ~1.25)	Substantial Equivalence		Substantial Equivalence		Substantial Equivalence		Substantial Equivalence		Substantial Equivalence	

d. Two-sided 90% confidence intervals for cellular composition data at Time Point 4 hours.

Time Point 4 hours	WBC		RBC		PLT		PLT Recovery		Concentration Factor	
	Subject	Predicate	Subject	Predicate	Subject	Predicate	Subject	Predicate	Subject	Predicate
Data (*n*=20)	7.8	8.2	0.20	0.22	706	728	59.0%	61.3%	4.01	4.14
	7.6	7.4	0.22	0.20	672	708	68.6%	72.8%	4.67	4.92
	9.8	9.6	0.32	0.32	908	874	68.1%	66.1%	4.63	4.46
	9.8	9.6	0.14	0.14	1318	1248	80.4%	76.7%	5.47	5.18
	15.6	15.0	0.80	0.74	1054	1018	74.2%	72.2%	5.04	4.87
	13.2	12.8	0.44	0.44	960	932	72.8%	71.2%	4.95	4.80
	8.0	7.8	0.22	0.20	798	784	68.6%	67.9%	4.67	4.58
	14.2	14.0	0.42	0.42	716	690	66.2%	64.3%	4.50	4.34
	11.4	11.4	0.56	0.56	984	976	66.1%	66.0%	4.49	4.46
	13.0	12.4	0.32	0.28	1168	1106	70.4%	67.2%	4.79	4.53
	13.6	13.2	0.48	0.44	956	944	71.7%	71.4%	4.88	4.82
	7.8	7.8	0.22	0.22	794	744	69.1%	65.2%	4.70	4.40
	14.2	13.6	0.44	0.44	670	720	61.6%	66.7%	4.19	4.50
	10.2	9.8	0.34	0.28	966	942	78.1%	76.7%	5.31	5.18
	9.8	9.2	0.16	0.16	1322	1264	73.6%	70.9%	5.01	4.79
	15.6	14.6	0.82	0.74	1028	956	80.8%	75.7%	5.50	5.11
	12.6	12.8	0.28	0.34	1198	1162	73.1%	71.4%	4.97	4.82
	11.2	11.2	0.56	0.54	1018	958	74.5%	70.6%	5.06	4.77
	7.4	7.0	0.20	0.20	722	692	73.2%	70.7%	4.98	4.77
	7.8	7.6	0.22	0.20	654	608	57.9%	54.3%	3.94	3.66
Mean	11.03	10.75	0.37	0.35	930.6	902.7	70.4%	69.0%	4.79	4.65
Ratio	1.025		1.035		1.028		1.021		1.028	
S.D.	0.028		0.085		0.039		0.039		0.039	
90% C.I.	0.010		0.031		0.014		0.014		0.014	
two-sided 90% C.I.	1.014 ~ 1.035		1.004 ~ 1.067		1.014 ~ 1.043		1.006 ~ 1.035		1.014 ~ 1.043	
(0.8 ~1.25)	Substantial Equivalence		Substantial Equivalence		Substantial Equivalence		Substantial Equivalence		Substantial Equivalence	

We evaluated the substantial equivalence of two devices using the method of two-sided 90% confidence intervals. If two-sided 90% confidence intervals for the ratio of subject device parameter to predicate device parameter is located between 0.80 and 1.25, subject device can be determined as substantial equivalence.

In conclusion, the output from the subject device demonstrated that its cellular composition and functional characteristics is substantially equivalent to the output from the predicate device.

Biocompatibility testing

The biocompatibility testing has been performed on the sterilized finished form of Dr.PRP according to ISO 10993-1. The platelet-rich plasma (PRP) prepared by the Dr.PRP is intended to be mixed with autograft and/or allograft bone prior to application to a bony defect and therefore the Dr.PRP is categorized as external communicating device which indirectly contacts blood with limited exposure

(contact of < 24 hrs). All biocompatibility tests have been carried out at Korea Testing Laboratory (KTL, Wonju, Korea) in good laboratory practice (GLP) conditions.

In addition, the bacterial endotoxin testing was performed using the methods described in ANSI/AAMI ST72.

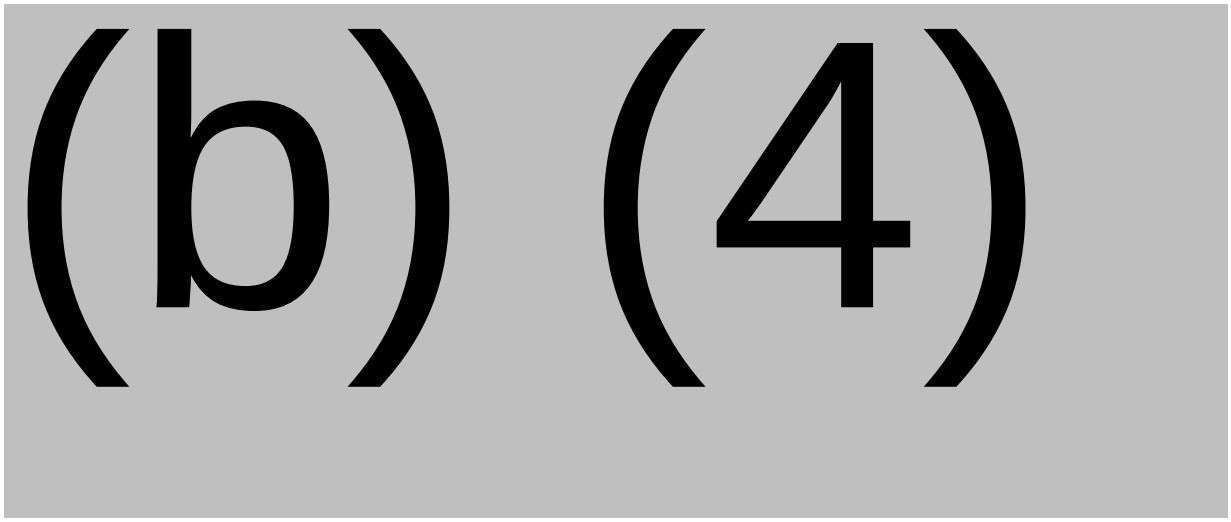
The following tests were included.

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity (acute)
- Pyrogenicity
- Material-mediated
- Hemolysis
- Pyrogenicity
- Endotoxin-mediated

The Dr.PRP has undergone biocompatibility tests in accordance with ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and bacterial endotoxin tests in accordance with ANSI/AAMI ST72 "Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing." The above-mentioned results show the device to be biocompatible and the product to be non-pyrogenic.

Sterilization validation

The sterilization validation of Dr.PRP was carried out according to the protocol relating to the requirements described in (b) (4)



Shelf-life validation

It is evaluated that there will be no influence to the quality performance of the packaging even by setting up shelf-life up to 3 year as the result of confirmation of physical and chemical stability and effectiveness through accelerated aging test and real time stability study data of samples irradiated (b) (4) kGy for evaluation of packaging materials according to related standards of ASTM and ISO.

- Storage conditions: temperature 35.6°F(2°C) - 86°F(30°C)
- Shelf-life: 3 years

Summary
Based on the performance data as documented in the pivotal performance testing, the Dr.PRP was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

The characteristics and intended use of the Dr.PRP is similar to predicate device, and the predicate device and Dr.PRP are identical in that they are disposable (supplied after being sterilization) device. In addition, performance data was checked to confirm substantial equivalence, and the safety of the equipment was demonstrated.