510(k) Summary of Safety and Effectiveness

Haemonetics PCS®2 Plasma Collection System with Revision K Software

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Device Information:

Proprietary Name:	PCS®2 Plasma Collection System
Common Name:	System for Plasma Aphaeresis
Classification Name:	Automated Blood Cell Separator (CFR 864.9245)
Regulatory Class:	Class II per 21 CFR 864.9245 and "*Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle*" dated November 2007.
Product Code:	PCS®2: GKT

Indications For Use:
The PCS®2 System is intended for use as an automated cell separator system and blood component collector in conjunction with single use sterile disposable sets. Products that can be collected using the PCS®2 System LN6002 automated cell separator include source plasma, plasma for reinfusion and plasma & leukocytes.

Products that can be collected using the PCS®2 LN6002 System with software revision K are source plasma and plasma for reinfusion only.

The LN625HS and LN625B are disposable centrifuge bowls designed for use with the PCS®2 LN6002 and the LN620 Disposable Harness, for the collection of source plasma and plasma for reinfusion, with or without saline compensation.

Device Description:
The PCS®2 System is designed for separation of whole blood by centrifugation, collection of Platelet Poor Plasma or Plasma and Leukocytes, and return of the remaining components to the donor. There have been no changes to the PCS®2 hardware or disposable sets since they were cleared via BK040025. BK040025 cleared Software Revision H (for use with the standard bowl LN625B), Software Revision J (same as Revision H but for use with the High Speed (HS) Bowl LN625HS) and the use of the HS Bowl (LN625HS). The software of the currently marketed PCS®2 system has been modified. The 510(k) clinical trials were performed using Rev J.1. The final commercial released software will be Rev K. The software has been modified to incorporate a new donor flow algorithm which used the Donor Pressure Monitor (DPM) as input to control the flow rate during draw and return. In addition to the software changes to support this new functionality, several changes have been made to provide better ease of use during operation.

Performance:
In Software Revision J.1, in terms of collection efficiency, there was an overall (combining needle and bowl combinations) improvement in:

- Procedure time reduce: -21.4%;
- Collection Efficiency Improvement: 32.2%
- Rate of Plasma Collection: +29.1%.

Donor tolerance was equivalent or superior to that of Software Revision H (p values $\geq$ 0.140 and donor reaction rates were mild.

Plasma quality was acceptable with Software Revision J.1. There was an expected higher cellular level in the plasma with increased speed for the standard bowl (LN625B) compared to the control group; however, the HS bowl (LN625HS) resulted in plasma with lower cellular levels than in the control group.

Claims are that the plasma product collected using the HS bowl with software Revision K contains leukocyte counts in collected plasma of $(0.49 \pm 2.48) \times 10^6$ /L, with a range of 0.02×10^6 /L to 23.22×10^6 /L; and platelet counts of $(13.43 \pm 14.23) \times 10^3$ /mL, with a range of 4.00×10^3 /mL to 86.00×10^3 /mL.

There were no clinically meaningful differences in plasma proteins between the software versions

Substantial Equivalence:
The substantial equivalence of the PCS®2 System with Revision K is substantiated by its similarity in intended use, design, and performance to the currently available version of this system (Revision H and J) cleared via BK040025. All fluid path materials in the modified and currently available disposables are identical.

	New	Predicate
Manufacturer	Haemonetics Corporation	Haemonetics Corporation
Trade/Device Name	PCS®2 Plasma Collection System	PCS®2 Plasma Collection System
Regulation Number	21 CFR 864.9245	21 CFR 864.9245
Regulation Name	Automated Blood Cell Separator	Automated Blood Cell Separator
Device Class	II as per "*Guidance for Industry and FDA Staff: Class II Special Controls Guidance*	II as per "*Guidance for Industry and FDA Staff: Class II Special Controls*

	Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle" dated November 2007.	*Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle"* dated November 2007.
FDA Product Code	GKT	GKT
510(k) number	BK080001	BK040025
Indications for Use (same)	The PCS®2 System is intended for use as an automated cell separator system and blood component collector in conjunction with single use sterile disposable sets. Products that can be collected using the PCS®2 System LN6002 automated cell separator include source plasma, plasma for reinfusion and plasma & leukocytes. Products that can be collected using the PCS®2 LN6002 System with software revision K are source plasma and plasma for reinfusion only. The LN625HS and LN625B are disposable centrifuge bowls designed for use with the PCS®2 LN6002 and the LN620 Disposable Harness, for the collection of source plasma and plasma for reinfusion, with or without saline compensation.	The PCS®2 System is intended for use as an automated cell separator system and blood component collector in conjunction with single use sterile disposable sets. Products that can be collected using the PCS®2 System LN6002 automated cell separator include source plasma and plasma. The LN625HS is a disposable centrifuge bowl designed for use with the PCS®2 LN6002 and the LN620 Disposable Harness, for the collection of source plasma and plasma for reinfusion, with or without saline compensation.
Hardware	There were no changes to the PCS®2 System hardware associated with the software modifications that are subject of this 510(k) application.	
Disposable	There were no changes to the PCS®2 System disposable set associated with the software modifications that are subject of this 510(k) application.	
Software	Software Revision K with update of new donor flow algorithm regulating draw and return rates based on donor venous pressure use with standard (LN625B) and HS bowl (LN625HS).	Software Revision H Platelet Poor Plasma Collection Protocol use with standard (LN625B) and Software Revision J for use with the HS bowl (LN625HS).
Performance	Overall: - Procedure time was reduced by -21.4%; - Collection efficiency improved 32.2%; and - Rate of plasma collection improved 29.1%. These claims are that the plasma product collected using the HS bowl with software Revision K contains leukocyte counts in collected plasma of $(0.49 \pm 2.48) \times 10^6$ /L, with a range of 0.02×10^6 /L to 23.22×10^6 /L; and platelet counts of $(13.43 \pm 14.23) \times 10^3$ /mL, with a range of 4.00×10^3 /mL to 86.00×10^3 /mL.	Mean procedure time (± Standard Deviation) was 59.40±13.05 minutes. Mean Blood processing rate (± Standard Deviation) was 37.76±3.26 ml/min. Mean Plasma Collection rate (± Standard Deviation) was 14.61±2.38 ml/min.