HAEMONETICS®

510(k) Summary

Date: July 20, 2017

Submitter:
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184

Contact:
Julie A. Ryan
Director, Regulatory Affairs
Phone: 781-356-9682
Fax: 781-356-3558
Email: julie.ryan@haemonetics.com

Device Information:

Trade Name:	Haemonetics PCS 300 Plasma Collection System
Common Name:	Automated Blood Cell Separator
Classification Name:	Separator, Automated, Blood Cell, Diagnostic
Regulation Number:	21 CFR 864.9245
Product Code:	GKT
Device Class:	2

Device Characteristics Summary:
The subject of this Special 510(k) is the Haemonetics PCS 300 Plasma Collection System. The PCS 300 is designed for separation of whole blood by centrifugation, collection of plasma, and return of the remaining components to the donor. The PCS 300 is the next generation of the predicate Haemonetics PCS2 Plasma Collection System.

The plasma collected by the PCS 300 may be designated for use in therapeutic transfusion or be conserved, used as source plasma, and subsequently fractionated into plasma-derived products.

Indications for Use:
The PCS 300 Plasma Collection System is intended for use as an automated cell separator system and blood component collector in conjunction with single-use sterile disposable sets, with or without saline compensation.

Products that can be collected using the PCS 300 system include source plasma and plasma for transfusion.

HAEMONETICS®

Non-Clinical Testing Summary:

The following non-clinical performance testing was submitted in support of a determination of substantial equivalence between the subject and predicate device. A summary of the performance testing is presented below in Table 1. Test data demonstrates that the device met all performance requirements, and that the subject device is as safe, as effective, and performs as well as or better than the predicate device.

Table 1: Summary of Performance Studies

Test Name	Test Report #	Test Intent	Test Result
Transportation	TR-SHP-100342	To verify device functions as intended after shipping and handling.	Passed
Electromagnetic Compatibility	TR-ELE-100828-A	To verify compliance with EMC requirements per IEC 60601-1-2.	Passed
Electrical Safety	TR-ELE-100831	To verify compliance with electrical safety requirements per IEC 60601-1.	Passed
Wireless Coexistence	TR-ELE-100830	To verify wireless coexistence of the PCS 300 with potential interference appliances.	Passed
Software Verification	TR-SOF-100602	To verify that PCS 300 software functions as intended and meets all design requirements.	Passed

Comparison to Predicate:

The Haemonetics PCS 300 Plasma Collection System is substantially equivalent to the Haemonetics PCS2 Plasma Collection System most recently cleared under BK150292. The PCS 300 is intended for use with the same disposables as the predicate device and in the same operating environment with the same donor/operator population. The indications for use are the same. The manner in which the software protocol operates to process blood and collect plasma is the same. The technological characteristics of the subject device differ from the predicate only in select additional hardware and software features that do not impact the clinical functionality of the device. These differences do not render the device non-substantially equivalent because non-clinical testing has demonstrated that the subject device is as safe and effective as the predicate and the results of verification and validation have not raised different questions of safety and effectiveness than the predicate.

A summary comparison is presented below in Table 2.

HAEMONETICS®

Table 2: Comparison of the PCS 300 to the Predicate PCS2

	Predicate **PCS2 Plasma Collection System (BK150292)**	**Subject** **PCS 300 Plasma Collection System**
Manufacturer	Haemonetics Corporation	Same
Trade Name	Haemonetics PCS2 Plasma Collection System	Haemonetics PCS 300 Plasma Collection System
Common Name	Automated Blood Cell Separator	Same
Classification Name	Separator, Automated, Blood Cell, Diagnostic	Same
Regulation Number	21 CFR 864.9245	Same
Product Code	GKT	Same
Device Class	2	Same
Indications for Use	The PCS2 System is intended for use as an automated cell separator system and blood component collector in conjunction with single use sterile disposable sets, with or without saline compensation. Products that can be collected using the PCS2 System LN6002 with NA software revision K/K.1/K.2 or IE software revision H.1 are source plasma and plasma for reinfusion only.	Same The PCS 300 Plasma Collection System is intended for use as an automated cell separator system and blood component collector in conjunction with single-use sterile disposable sets, with or without saline compensation. Products that can be collected using the PCS 300 system include source plasma and plasma for transfusion.
Hardware		
Pumps	Peristaltic pumps, 1 ml per rotation	Same
Effluent Line Sensor	Absorbance optical system (LED beam across transparent tubing permitting detection of air/plasma interface and plasma/buffy coat interface)	Same
Air Detectors	Ultrasonic	Same
Pressure Sensor (DPM)	Donor Pressure Monitor with interlock to regulate pump speed based on pressure	Same
Wireless	Yes	Yes

	Predicate PCS2 Plasma Collection System (BK150292)	Subject PCS 300 Plasma Collection System
Connectivity		
Centrifuge	Nominal speed = 7500 rpm	Same, with updated cover with locking mechanism
Bowl Optics	Absorbance optical system detecting the interface between the plasma and the red cells in the separation bowl	Same, but digital instead of analog signal
Valves	Electrical valves	Pneumatic valves
Plasma Weigher	Front load cell connected to a rotating arm which allows the device cover to be closed	Fixed front load cell
User Interface	Membrane panel with monochrome screen	8” color touch screen
Bar Code Reader	Optional; used for donation ID and target download	Embedded; used for operator, donor, donation, disposable set readings
Donor Display	4 colored LEDs showing donor flow status	Digital display on each side of the device, communicates info to donor about the procedure
Anticoagulant (AC) Weigher	None	Load cell on pole with hook for hanging the AC bag
Status Beacon	None	Beacon light above touch screen display, indicates status of procedure
Software		
Self-Test	Yes	Same
Plasma Target Selection	Yes, manual and through server if connected	Same
Modifiable Parameters	Yes, cuff pressure, draw and return speed, max plasma per cycle, saline	Same
Express Donor Draw and Return Flow Control	Yes	Same
AC Short Prime	Yes	Same
Disposable Detection	Detection of the installed disposables: bowl, DPM, line sensor and plasma container	Same, with additional detection of line sensor cover; disposables bar codes can also be scanned
Diagnostics	Manual diagnostics	Manual and automated diagnostics via connectivity

HAEMONETICS®

	Predicate PCS2 Plasma Collection System (BK150292)	Subject PCS 300 Plasma Collection System
Notifications	Single screen, no reference number for notification or error type	Main and hints screens, individual ID for each notice
Procedure Technical Data	Records data for up to 100 procedures	Same, with increased storage
Phlebotomy Workflow	No	Yes
User Access Control	No	Yes
Disposable Sets		
PCS2 and PCS 300 operate using the same previously-cleared disposable sets.		

_____ _____

Julie A. Ryan
Director, Regulatory Affairs
Haemonetics Corporation

Date