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510(k) Summary

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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 with software version 1.2.0. 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 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.

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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
Software Verification	TR-SOF-100648	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 with software version 1.2.0 is substantially equivalent to the Haemonetics PCS 300 Plasma Collection System cleared under BK170045. 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 limited 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.

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Table 2: Comparison of the PCS 300 with Software Version 1.2.0 to the Predicate PCS 300

	Predicate **PCS 300 Plasma Collection System (BK170045)**	**Subject** **PCS 300 Plasma Collection System w/ Software Version 1.2.0**
Manufacturer	Haemonetics Corporation	Same
Trade Name	Haemonetics PCS 300 Plasma Collection System	Same
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 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.	Same
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

	Predicate PCS 300 Plasma Collection System (BK170045)	Subject PCS 300 Plasma Collection System w/ Software Version 1.2.0
Wireless Connectivity	Yes	Same
Centrifuge	Nominal speed = 7500 rpm	Same
Bowl Optics	Digital absorbance optical system detecting the interface between the plasma and the red cells in the separation bowl	Same
Valves	Pneumatic valves	Same
Plasma Weigher	Fixed front load cell	Same
User Interface	8” color touch screen	Same
Bar Code Reader	Embedded; used for operator, donor, donation, disposable set readings	Same
Donor Display	Digital display on each side of the device, communicates info to donor about the procedure	Same
Anticoagulant (AC) Weigher	Load cell on pole with hook for hanging the AC bag	Same
Status Beacon	Beacon light above touch screen display, indicates status of procedure	Same
Software		
Self-Test	Yes	Same
Plasma Target Selection	Yes, manual and through server if connected	Same, with option to target based on Plasma Volume/Weight or Collection Volume
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

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	Predicate PCS 300 Plasma Collection System (BK170045)	Subject PCS 300 Plasma Collection System w/ Software Version 1.2.0
Disposable Detection	Detection of the installed disposables: bowl, DPM, line sensor and plasma container; detection of line sensor cover; disposables bar codes can also be scanned	Same
Diagnostics	Manual and automated diagnostics via connectivity	Same
Notifications	Main and hints screens, individual ID for each notice	Same
Procedure Technical Data	Records data for up to 100 procedures	Same
Phlebotomy Workflow	Yes	Same
User Access Control	Yes	Same
Disposable Sets		
Disposables	Previously-cleared disposable bowls, bottles, and harnesses	Same

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Date