HAEMONETICS®

510(k) Summary

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Submitter:
Haemonetics Corporation
125 Summer Street
Boston, MA 02110

Contact:
Julie A. Ryan
Sr. Director, Regulatory Affairs
Phone: 781-690-0575
Fax: 781-356-3558
Email: julie.ryan@haemonetics.com

Device Information:

Trade Name:	NexSys PCS® Plasma Collection System with Persona™ Technology
Common Name:	Automated Blood Cell Separator
Classification Name:	Separator, Automated, Blood Cell, Diagnostic
Regulation Number:	21 CFR 864.9245
Review Panel:	Hematology
Product Code:	GKT
Device Class:	2

Device Characteristics Summary:
The Haemonetics NexSys PCS® Plasma Collection System with Persona™ Technology includes the Persona Plasma Pooling Bottle and ability to integrate with NexLynk DMS® Donor Management System. It is designed for separation of whole blood by centrifugation, collection of plasma, and return of the remaining components to the donor.

Proprietary Persona Technology incorporates the new Persona nomogram which is tailored to each donor's individual characteristics. When Persona is enabled, the target plasma volume is determined using each donor's height, weight, and hematocrit. The plasma collected by the NexSys PCS 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 NexSys PCS® Plasma Collection System with Persona™ Technology 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 NexSys PCS® system include source plasma and plasma for transfusion.

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-100731	To verify that NexSys PCS software functions as intended and meets all design requirements.	Passed

Clinical Testing Summary:
Clinical testing was submitted in support of a determination of substantial equivalence between the subject and predicate device. A summary of the clinical testing is presented below in Table 2.

Haemonetics conducted a prospective, double-blinded, randomized, controlled, multicenter clinical trial to demonstrate the safety and effectiveness of the NexSys PCS® Plasma Collection System with Persona™ Technology. The data provide evidence that plasmapheresis with the NexSys PCS with Persona Technology is non-inferior to the control with regard to the incidence rates of significant hypotensive adverse events. Secondary analysis with regard to total plasma volume collected per procedure demonstrated that more plasma volume per procedure was collected using the NexSys PCS with Persona Technology.

Clinical data demonstrates that the study met the primary endpoint and that the NexSys PCS Plasma Collection System with Persona Technology is substantially equivalent to the predicate device.

Table 2: Summary of Clinical Studies

Test Name	Test Report #	Test Intent	Test Result
IMPACT Clinical Trial	TR-CLN-100467	To demonstrate safety and effectiveness of the NexSys PCS Plasma Collection System with Persona Technology.	The primary endpoint was met.

Comparison to Predicate:

The Haemonetics NexSys® PCS Plasma Collection System with Persona™ Technology is substantially equivalent to the Haemonetics NexSys PCS (PCS 300) Plasma Collection System with YES® Technology cleared under BK180185. The NexSys PCS is intended for use in the same operating environment with the same donor/operator population as the predicate device. 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 features of the embedded software that enable use of the Persona nomogram and do not impact the clinical functionality of the device. These differences do not render the device non-substantially equivalent because clinical and 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 3.

Table 3: Comparison of the NexSys PCS® Plasma Collection System with Persona™ Technology to the Predicate

	Predicate **NexSys PCS® (PCS 300) Plasma Collection System w/ YES® Technology (BK180185)**	**Subject** **NexSys PCS® Plasma Collection System with Persona™ Technology**
Manufacturer	Haemonetics Corporation	Same
Trade Name	NexSys PCS® (PCS 300) Plasma Collection System w/ YES™ Technology	NexSys PCS® Plasma Collection System w/ Persona™ Technology
Common Name	Automated Blood Cell Separator	Same
Classification Name	Separator, Automated, Blood Cell, Diagnostic	Same
Regulation Number	21 CFR 864.9245	Same
Review Panel	Hematology	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.	The NexSys PCS® Plasma Collection System with Persona™ Technology 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 NexSys PCS® system include source plasma and plasma for transfusion.

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Hardware		
Pumps	Peristaltic pumps, 1 ml per rotation	Same
Effluent Line Sensor	Absorbance optical system (LED beam across transparent tubing) for 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 Connectivity	Yes	Same
Centrifuge	Nominal speed = 7500 rpm	Same
Bowl Optics	Absorbance optical system for detection of air/plasma interface and plasma/buffy coat interface 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	Embedded or external USB; used for operator, donor, donation, disposable set readings
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 addition of plasma target programming based on Persona™ nomogram
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: DPM, line sensor tubing, and plasma container; detection of line sensor cover and centrifuge cover lock; disposables bar codes can also be scanned	Same
Diagnostics	Manual and automated diagnostics	Same
Notifications	Main and hints screens, individual ID for each notice	Same
Procedure Technical Data	Records data for up to 100 procedures	Records data for up to 10,000 procedures
Phlebotomy Workflow	Yes	Same
User Access Control	Yes	Same
Disposable Sets		
Disposables	Previously-cleared disposable bowls, bottles, and harnesses	Same, with addition of a larger Persona™ plasma pooling bottle

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Date