HAEMONETICS®

510(k) Summary

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Device Information:

Trade Name:	NexSys PCS® Plasma Collection System with Persona PLUS 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

Legally Marketed Predicate Device:

Predicate #	Predicate Trade Name	Product Code
BK220798	NexSys PCS Plasma Collection System with Express®Plus Technology	GKT
BK200498	NexSys PCS Plasma Collection System with Persona Technology	GKT

Device Description Summary:
The Haemonetics NexSys PCS® Plasma Collection System is designed for separation of whole blood by centrifugation, collection of plasma, and return of the remaining components to the donor. The plasma may be designated for use in therapeutic transfusion or be conserved and used as source plasma, that is subsequently fractioned into plasma-derived products.

Intended Use/Indications for Use:
The NexSys PCS® plasma collection system with Persona or Persona PLUS 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.

Using the 0625Q-00 bowl, the NexSys PCS® system with Express®Plus Technology is intended to collect source plasma only.

Indications for Use Comparison:
There is no change to the indications for use of the NexSys PCS® Plasma Collection System with Persona PLUS Technology from its predicate device.

Technological Comparison:
There is no change to the material, composition, principle of operation, or energy source from the predicate NexSys PCS® (BK220798). The device functions with the same intended use for the collection of plasma via apheresis.

There is no change to software of the product specific to this change to introduce Persona PLUS Technology.

Through the discussion on substantial equivalence and the clinical data provided, it is concluded that the changes associated with the NexSys PCS do not change the benefit-risk profile of the NexSys PCS device.

Non-Clinical Summary & Conclusions
There was no new non-clinical testing required.

Clinical Summary & Conclusions
A prospective, randomized, controlled, multicenter, pivotal clinical trial to evaluate the safety and effectiveness of the NexSys PCS with Persona PLUS Technology was conducted.
Through the clinical data provided, it is demonstrated that there is no change to the benefit-risk profile of the NexSys PCS device with the introduction of the Persona PLUS Technology. The proposed device is as safe and effective as its predicate and reference device.