HAEMONETICS®

510(k) Summary

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Device Information:

Trade Name:	NexSys PCS® Plasma Collection System with Express®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
BK200498	NexSys PCS Plasma Collection System with Persona Technology	GKT
BK170099	Amicus Separator System	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, used as source plasma, and subsequently fractioned into plasma-derived products.

The Express®Plus technology updates the NexSys PCS® software algorithm and device firmware, and enables the use of the new 0625Q-00 Plasma bowl.

Intended Use/Indications for Use:
The NexSys PCS® plasma collection system with Express®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 Express®Plus Technology. The currently cleared indications of the predicate (BK200498) continue to be supported with the software upgrade. The 0625Q-00 plasma bowl has a subset of these indications for the collection of source plasma only.

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

Technological Comparison:
There is no change to the material, composition, principle of operation, or energy source from the predicate NexSys PCS® (BK200498). The device functions with the same intended use for the collection of plasma via apheresis.

The change in design for the subject NexSys PCS® Plasma Collection System with Express®Plus Technology introduces enhancements to the flow control algorithm and enables the use of the 0625Q-00 plasma bowl. These changes are within the parameters of the AMICUS

reference device (BK170099). Through the discussion on substantial equivalence and the bench testing provided, it is concluded that the changes associated with the Express®Plus Technology upgrade do not change the benefit-risk profile of the NexSys PCS® system.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The non-clinical bench testing and comparison to the predicate and reference devices show the subject NexSys PCS® Plasma Collection System with Express®Plus Technology to be substantially equivalent to the devices on the market and that there is no impact to the safety and effectiveness of the device. Additional analysis of TPLC/MAUDE database for related adverse events for product code GKT and relevant clinical literature and expert analysis, supports the safety and effectiveness of the proposed changes to the NexSys PCS® device and that there is no change to the benefit-risk profile of the device.

Results from the non-clinical bench testing demonstrate that the NexSys PCS Plasma Collection System with ExpressPlus Technology and is as safe and effective, and performs as well as its proposed predicate device.