Section 7- 510(k) Summary of Safety and Effectiveness

7.1 **Statement**	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92
7.2 **Submitter**	Haemonetics Corporation 400 Wood Road Braintree, MA. 02184-9114
7.3 **Company Contact**	Susan Finneran Regulatory Affairs Manager 355 Wood Rd. Braintree, MA. 02184-9114 781-356-9220
7.4 **Device Name**	**Proprietary Name:** MCS+LN9000 **Common Name:** LN9000 **Classification Name:** Automated Blood Cell Separator
7.5 **Predicate Legally Marketed Devices**	The MCS+9000 device and 994CF-CPP disposable set that is the subject of this premarket notification is substantially equivalent to the MCS+9000 device and 994CF-CPP disposable set previously cleared via BK010035.
7.6 **Device Description**	The MCS+ 9000 (SDPE software protocol) and associated disposable set 994CF-CPP are intended to be used to collect two units of platelets (leukoreduced) or one unit of platelets (leukoreduced) and plasma. The hardware, software, and disposable set are considered to be an automated blood cell separation system.

7.7
Device Indications and Intended use

The Haemonetics extended Storage Platelet and Plasma Set with Saline Compensation, PALL filter (LRF-XL), is intended to be used to collect one unit of platelets, leukocyte reduced (with or without plasma). Additionally, the set may be used to collect two units of platelets, leukocyte reduced. The collected platelets may be stored up to 7 days when collected using the LN994CF-CPP and coupled with 100% screening for bacterial contamination with a device cleared for that purpose with its recommended method prior to transfusion.

TABLE 7.1 Table of Substantial Equivalence

Characteristics	Predicate Device LN9000 (BK010035)	Proposed Device LN9000 (current 510k)
Hardware	**MCS+ LN9000**	**MCS+ LN9000**
Disposable	**NL994CF-CPP**	**LN 994CF-CPP**
Protocol	**SDP revision E platelet/ plasma collection**	**SDP revision E platelet/ plasma collection**
Intended use	The Haemonetics extended Storage Platelet and Plasma Set with Saline Compensation, PALL filter (LRF-XL), is intended to be used to collect one unit of platelets, leukocyte reduced (with or without plasma). Additionally, the set may be used to collect two units of platelets, leukocyte reduced. The collected platelets may be stored up to 5 days.	The Haemonetics extended Storage Platelet and Plasma Set with Saline Compensation, PALL filter (LRF-XL), is intended to be used to collect one unit of platelets, leukocyte reduced (with or without plasma). Additionally, the set may be used to collect two units of platelets, leukocyte reduced. The collected platelets may be stored up to 7 days when collected using the LN994CF-CPP and coupled with 100% screening for bacterial contamination with a device cleared for that purpose with its recommended method prior to transfusion.

Product Quality	In vitro parameters for SDPE not greater than 20% difference compared to previous protocol with 90% confidence.	In vitro testing at the end of storage within acceptable range. 95% confidence (two-sided) that stored platelet in vivo recoveries are ≥ 66.7% of fresh platelets 95% confidence (two-sided) that stored platelet in vivo survivals ≥ 58% of fresh platelets
Bag Specifications 994CF-CPP	Up to 5.0 x 1011 platelets may be stored in the 994CF-CPP bag for up to 5 days. The concentration must be in the range of 1000-2600 x 10^3 platelet / µL Minimum single platelet volume is 200ml	Up to 5.0 x 1011 platelets may be stored in the 994CF-CPP bag for up to 7 days. The concentration must be in the range of 1000-2100 x 10^3 platelet / µL Single platelet volume is in the range of 200-400mls.

Applicant 

Date 11/9/05