

Section 6- 510(k) Summary of Safety and Effectiveness

6.1 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

6.2 Submitter Haemonetics Corporation
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6.4 Device Name **Proprietary Name:** Haemonetics 4ml Sampling System
Common Name: Platelet Transfer Set.
Classification Name: Transfer Set

6.5 Predicate Legally Marketed Devices The Haemonetics 4ml Sampling System is substantially equivalent to the Charter Medical Platelet Transfer set that **was** cleared via BK960043.

6.6 Device Description The 4ml sampling system is a platelet transfer device that is intended to be sterile connected to a currently commercialized platelet storage container.

6.7

Device

Indications and

Intended use

The Haemonetics 4ml sampling system is intended to be sterile connected to a platelet storage container for the purpose of obtaining a 4 milliliter sample of platelets

Table of Substantial Equivalence

Device Name	Platelet Sampling System	Haemonetics 4ml Sampling System
Intended use	Charter Medical Platelet Sampling System is designed specifically for transferring aphaeresis platelet samples safely from the Mother bag (and Split bags) to an automated cell culture system's vacuum bottles.	The Haemonetics 4ml sampling system is intended to be sterile connected to a platelet storage container for the purpose of obtaining a 4 milliliter sample of platelets.
Method of Connection	Sterile connection of tubing to platelet bag	Sterile connection of tubing to platelet bag
Method of transfer	Gravity flow regulated using clamps or vacuum using a syringe	Gravity flow regulated using clamps
Materials	Various Plastics, PVC Tubing	Various Plastics, PVC Tubing,
Sterilization/ Labeling	Sterile, Single Use	Sterile, Single Use

Applicant



Date

1/15/04