

## Section 8- 510(k) Summary of Safety and Effectiveness

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**8.1**  
**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

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**8.2**  
**Submitter** Haemonetics Corporation  
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Braintree, MA. 02184-9114

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**8.3**  
**Company** Susan Finneran  
**Contact** Director Regulatory Affairs, Donor Division  
355 Wood Road  
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**8.4**  
**Device Name** **Proprietary Name:** Cymbal Automated Blood Collection System  
**Common Name:** Cymbal  
**Classification Name:** Automated Blood Cell Separator

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**8.5**  
**Predicate** The Haemonetics Cymbal Automated Blood Collection System that is the  
**Legally** subject of this submission is substantially equivalent to the Cymbal Automated  
**Marketed** Blood Collection system cleared via BK060057.  
**Devices**

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**8.6****Device****Description**

The Cymbal Automated Blood Collection System is an automated blood cell separation system intended to be used to two units of filtered red cells or one unit of filtered red cells in the event of an aborted procedure.

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**8.7****Device****Indications and****Intended use****Indications for use:**

The Cymbal Automated Blood Collection System is intended to collect two units of CP2D/AS-3 Red Blood Cells, Leukocytes Reduced from autologous and allogeneic donors. One unit of CP2D/ AS-3 Red Blood Cells, Leukocytes Reduced may be collected in the event of a terminated procedure during the third draw phase.

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The following page contains a table comparing the new versus the predicate device.

**TABLE 8.1 TABLE OF SUSTANTIAL EQUIVALENCE**

<b>Characteristics</b>	<b>Predicate Device- Cymbal Automated Blood Collection System, 2-unit Filtered Protocol</b>	<b>Proposed Device – Cymbal Automated Blood Collection System, 2-unit Filtered Protocol</b>
<b>Protocol</b>	Two Unit Filtered Red Cell	Two Unit Filtered Red Cell
<b>Hardware</b>	Cymbal Automated Blood Collection System	Cymbal Automated Blood Collection System
<b>Disposable</b>	List number: 311-00	List number: 311-00
<b>Intended Use</b>	The Cymbal Automated Blood Collection System is intended to collect two units of leukoreduced red cells collected/ stored in CP2D/ AS-3 from autologous and allogeneic donors.	The Cymbal Automated Blood Collection System is intended to collect two units of CP2D/AS-3 Red Blood Cells, Leukocytes Reduced from autologous and allogeneic donors. One unit of CP2D/ AS-3 Red Blood Cells, Leukocytes Reduced may be collected in the event of a terminated procedure during the third draw phase
<b>Product Quality</b>	Leukoreduction yields units with $<5 \times 10^6$ WBCs/unit.  Red cell recovery $>85\%$ post- filtration  Hemolysis level $<1\%$ at day 42 of storage.	Leukoreduction yields units with $<5 \times 10^6$ WBCs/unit.  That each Red Blood Cell contains a minimum absolute red blood cell volume of 150mls in $\geq 95\%$ of the units tested (a mean of 150mls for the two unit collections is also acceptable).  Hemolysis level $<1\%$ at day 42 of storage.

Applicant 

Date 7/10/08