

## 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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**8.4 Device Name** **Proprietary Name:** Haemonetics® Model 215 Automated Glycerolization / Deglycerolization System  
**Common Name:** ACP 215  
**Classification Name:** Processing System for Frozen Blood

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**8.5 Predicate Legally Marketed Devices** The Haemonetics ACP 215, which is the subject of this submission, is substantially equivalent to the previously cleared ACP 215 cleared via BK030062.

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**8.6**

**Device Description** The ACP 215 is an automated cell processing system intended to be used glycerolize and red blood cells.

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

*The ACP 215 is intended to glycerolize and deglycerolize red blood cells derived from whole blood that have been stored in any approved anticoagulant/additive solution for up to 6 days at 1-6°C prior to glycerolization.*

*Red blood cells, derived from whole blood collections and non-leukoreduced, that have been collected and stored in CPDA-1, glycerolized using the ACP 215 and frozen at -65°C or colder and deglycerolized using the ACP 215 and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days.*

*In addition, red blood cells that have been collected and stored in CPD/AS-1, or CP2D/AS-3, leukoreduced, glycerolized using the ACP 215, frozen at -65°C or colder, deglycerolized by the ACP 215, and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days.*

*Red blood cells collected in any other anticoagulant / additive solution will be labeled with a 24-hour outdate.*

*Red cells, non-leukoreduced, that were manually glycerolized using the 40% W/V Glycerol (Valeri Method) and frozen at -65°C or colder may be deglycerolized using the ACP 215 and labeled with a 24 hour outdate.*

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

<b>Characteristics</b>	<b>Predicate Device ACP 215 System</b>	<b>Proposed Device – ACP 215 System</b>
<b>Protocol</b>	Automated Glycerolization/ Deglycerolization	Automated Glycerolization/ Deglycerolization
<b>Hardware</b>	ACP 215	ACP 215
<b>Disposable</b>	LN225 and LN235-00 or LN236	LN225 and LN235-00 or LN236
<b>Washing Solution</b>	12 %NaCl 0.9% NaCl/ 0.2gm Glucose	12 %NaCl 0.9% NaCl/ 0.2gm Glucose
<b>Intended Use</b>	<p><i>The ACP 215 is intended to glycerolize and deglycerolize red blood cells derived from whole blood that have been stored in any approved anticoagulant/additive solution for up to 6 days at 1-6°C prior to glycerolization.</i></p> <p><i>Red blood cells, derived from whole blood collections and non-leukoreduced, that have been collected and stored in CPDA-1, glycerolized using the ACP 215 and frozen at -80°C and deglycerolized using the ACP 215 and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days.</i></p> <p><i>In addition, red blood cells that have been collected and stored in CPD/AS-1, or CP2D/AS-3, leukoreduced, glycerolized using the ACP 215, frozen at -65°C or colder, deglycerolized by the ACP 215, and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days.</i></p> <p><i>Red blood cells collected in any other anticoagulant / additive solution will be labeled with a 24-hour outdate.</i></p> <p><i>Red cells, non-leukoreduced, that were manually glycerolized using the 40% W/V Glycerol (Valeri Method) and frozen at -65°C or colder may be deglycerolized using the ACP 215 and labeled with a 24 hour outdate</i></p>	<p><i>The ACP 215 is intended to glycerolize and deglycerolize red blood cells derived from whole blood that have been stored in any approved anticoagulant/additive solution for up to 6 days at 1-6°C prior to glycerolization.</i></p> <p><i>Red blood cells, derived from whole blood collections and non-leukoreduced, that have been collected and stored in CPDA-1, glycerolized using the ACP 215 and frozen at -65°C or colder and deglycerolized using the ACP 215 and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days.</i></p> <p><i>In addition, red blood cells that have been collected and stored in CPD/AS-1, or CP2D/AS-3, leukoreduced, glycerolized using the ACP 215, frozen at -65°C or colder, deglycerolized by the ACP 215, and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days.</i></p> <p><i>Red blood cells collected in any other anticoagulant / additive solution will be labeled with a 24-hour outdate.</i></p> <p><i>Red cells, non-leukoreduced, that were manually glycerolized using the 40% W/V Glycerol (Valeri Method) and frozen at -65°C or colder may be deglycerolized using the ACP 215 and labeled with a 24 hour outdate.</i></p>
<b>Product Quality</b>	<p><b>Recovery:</b> 95% confidence that at least 90% units met the 80% minimum recovery</p> <p><b>Hemolysis:</b> 95% confident that 95% of the units</p>	<p><b>Recovery:</b> 95% confidence that at least 90% units met the 80% minimum recovery</p> <p><b>Hemolysis:</b> 95% confident that 95% of the units</p>

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Applicant *And*

Date 4/7/05