

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

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

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.

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 -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.

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° 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.

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