

**510(K) SUMMARY**

**Date:** January 11, 2000

**Sponsor:** Haemonetics Corporation  
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**Proprietary Name:** Haemonetics Model 215 Automated Glycerolization and  
Deglycerolization System  
  
Haemonetics LN225, Glycerolization Disposable Set  
  
Haemonetics LN235, Deglycerolization Disposable Set

**Classification Name:** Processing system for frozen blood (21 CFR 864.9145)

**Common or Usual Name:** Model 215  
  
LN225 Disposable Set  
  
LN235 Disposable Set

**Predicate Device:**

Predicate Device	FDA Reference #
Haemonetics 115 Cell Washing System Haemonetics Cell Wash Set (LN 7497)	BB-MF <del>          </del> BK840022 <sup>7</sup>
Haemonetics Closed System Technology used for collection of Apheresis Red Blood Cells:	
Haemonetics MCS+ LN 8150 Haemonetics Red Blood Cell and Plasma Apheresis Set (LN821)	BK940064
Haemonetics Red Blood Cell Apheresis Set (LN831)	BK950001
Haemonetics Red Blood Cell and Plasma Apheresis Set (LN823)	BK950063
Haemonetics Red Blood Cell Apheresis Set (LN833)	BK960006
Haemonetics Red Blood Cell Apheresis Set (LN832)	BK960022
Haemonetics Red Blood Cell and Plasma Apheresis Set (LN822)	BK960023
Haemonetics Red Blood Cell Apheresis Sets (LN831, LN832, LN833) for Allogeneic Donors	BK960095

**DEVICE DESCRIPTION**

The Haemonetics Model 215 Automated Glycerolization and Deglycerolization System is a lightweight, compact, centrifugal cell washing system. This system consists of four parts: the Model 215 machine, two single-use disposable sets, software, and AS-3 preservative solution.

**Machine**

The Model 215 machine is based on the MCS+ LN8150 platform. The components of the Model 215 machine include a Power Entry Module (PEM), a centrifuge, pumps, a display screen, a control panel, pressure monitors, pneumatic valves, ultrasonic air detectors, an optical line sensor, a stand-alone shaker, and a satellite printer.

**Glycerolization**

The LN225 Glycerolization disposable set is used with the Model 215 machine and the glycerolization protocol to prepare a red blood cell product for frozen storage. The glycerolization process consists of: (1) the computation of the appropriate quantity of glycerol solution to be delivered to the red blood cell product, and calculation of the appropriate glycerolization flow rate, (2) the delivery of the glycerol solution to the red blood cell product bag through a bacteria barrier filter, and 3) as the glycerol solution is delivered, automated mixing of the red blood cell product with the glycerol solution.

<sup>7</sup> Haemonetics' 115 Cell Washing System was cleared by FDA under BK840022 as Haemonetics Corporation Processing System for Frozen Blood.

The components of the LN225 glycerolization disposable set include a vented spike, a bacteria barrier filter, a Draw Pressure Monitor (DPM) filter, and heat sealed tubing.

### **Deglycerolization**

The LN235 Deglycerolization disposable set is used with the Model 215 machine and the deglycerolization protocol. Deglycerolization is performed on red cell products, which have been previously frozen and stored at -80 °C. This process has three phases: (1) dilution of the thawed frozen blood and the removal of the supernatant, (2) washing of the diluted thawed blood, and (3) resuspension of the washed red blood cells in AS-3 preservative solution before transfer into the red blood cell storage bag. The components of the LN235 deglycerolization disposable set include a solution connection assembly (two spikes and a luer), a bacteria barrier filter, a centrifugal blood-processing bowl, a Draw Pressure Monitor (DPM) filter, a System Pressure Monitor (SPM) filter, a red blood cell final product bag, a waste bag, and heat sealed tubing.

### **AS-3 Preservative Solution**

AS-3 preservative solution is a well known and well documented preservative used for storage of red blood cell products. The 300 mL size AS-3 preservative solution used with the Model 215 is manufactured by Haemonetics Corporation, Union, South Carolina. The Haemonetics AS-3 solution is produced in a facility designed and FDA inspected for the production of human IV drugs following current Good Manufacturing Practices. The solution is stored in a sealed flexible plastic container and has undergone quality control testing following current USP methods. The drug substances used in the Haemonetics AS-3 Solution formulation are all USP XXIII monograph ingredients.

### **Intended Use**

Haemonetics Model 215 Automated Glycerolization and Deglycerolization System glycerolizes and deglycerolizes red blood cell products in a closed system to allow for the extended storage of the deglycerolized red blood cell product for up to 14 days at 4 °C.

### **CLINICAL TEST RESULTS**

A total of 106 red blood cell units have been glycerolized and deglycerolized using the Model 215. The in vitro RBC quality data obtained on these 106 units demonstrate that red cell units glycerolized and deglycerolized using the Model 215 are processed in a closed system and can be stored for up to 14 days at 4 °C.

### **CONCLUSION**

The information presented in this Premarket Notification supports that red blood cell products glycerolized and deglycerolized using Haemonetics Model 215 Automated Glycerolization and Deglycerolization System are processed in a closed system and can be stored for up to 14 days at 4 °C.