

**Glycerolyte 57 Solution
510(k) Summary
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Date Prepared:

31 August 2018

Owner and Contact Person:

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Device Name(s):

Glycerolyte 57 Solution

The following disposable products are affected by the modifications described in this premarket notification:

Fresenius Kabi Article Code Number	Product Name
4A7831	Glycerolyte 57 Solution, 400 mL
4A7833	Glycerolyte 57 Solution, 500 mL

Common Name(s):

Glycerolyte 57 Solution

Classification Name:

21 CFR 864.9145 – Processing System for Frozen Blood

Classification Panel:

81 KSW (Hematology) – Processing System for Frozen Blood

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Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:

Fresenius Kabi is claiming substantial equivalence of the disposable products with the modifications described in this Traditional 510(k) to the currently marketed versions of the products distributed as Preamendments Medical Devices.

Device Description:

Glycerolyte 57 Solution:

Glycerolyte 57 Solution is a high concentration solution of glycerol lactate. It is added to Red Blood Cells prior to freezing as a cryoprotective agent in accordance with published protocols. The product is manufactured in glass bottles and is available in 400 mL and 500 mL volumes.

Modifications to the products described in this Traditional 510(k) are not intended to add, delete, or modify information regarding the description or usage of the device.

Modification of Existing Device:

Glycerolyte 57 Solution:

Glycerolyte 57 Solution is manufactured in a glass bottle with an elastomeric closure produced with Ethylene Propylene Diene Monomer (EPDM). The supplier of the EPDM material has discontinued production and the stopper will be produced with EPDM material from a newly qualified supplier. The EPDM from the new supplier has a different extractives profile relative to the material from the current supplier. No changes have been made to the materials, composition, or formulation of the solution, or to the sterilization, processing, or expiration dating of the finished product.

Statement of Intended Use:

A processing system for frozen blood is a device used to glycerolize red blood cells prior to freezing to minimize hemolysis (disruption of the red cell membrane accompanied by the release of hemoglobin) due to freezing and thawing of red blood cells and to deglycerolize and wash thawed cells for subsequent reinfusion.

Glycerolyte 57 Solution:

Glycerolyte 57 Solution is a high concentration glycerol cryopreservative processing solution for manufacture of Red Blood Cells, Frozen.

Modifications to the kits associated with this 510(k) are not intended to add, delete, or modify information as described in labeling regarding the intended use of the device or the disposable kits.

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Technological Characteristics as Compared to the Predicate Device:

Technological characteristics of the disposable products remain the same as currently defined. Modifications to the products associated with this Traditional 510(k) are not intended to add, delete, or modify information regarding the technological characteristics of the device.

Design Control Activities:

Design control activities for changes described in this Traditional 510(k) were conducted under Fenwal procedures for change control and assessment, risk assessment, and design verification and validation, in accordance with 21 CFR 820 Quality System Regulation requirements. Potential risks associated with the proposed changes were identified and testing was performed to validate that device function was maintained within established specifications.

Performance Data:

Existing performance testing and data remains valid for demonstrating disposable product performance. Additional testing and data described in this Traditional 510(k) was performed to validate that device function was maintained within established specifications.

Conclusions:

The Glycerolyte 57 Solution disposable products with the modifications described in this Traditional 510(k) are substantially equivalent to the current marketed preamendments versions of the devices.