Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

510(K) SUMMARY

Date Prepared:

September 28, 2018

510(k) Owner and Contact Person:

Owner/Operator	Owner/Operator Number: 9027285 Fresenius Kabi AG Bad Homburg, GERMANY 61346
Contact Name: Title: Address: Telephone: Fax: E-mail:	Shuiquan Jing Manager, Regulatory Affairs Fresenius Kabi USA, LLC Three Corporate Drive, 2nd Floor Lake Zurich, IL 60047 USA 847-550-2280 847-550-2960 shuiquan.jing@fresenius-kabi.com
Official Correspondent: Title: Address: Telephone: Fax: E-mail:	Cheryl Roscher Vice President, Regulatory Affairs Fresenius Kabi USA, LLC Three Corporate Drive, 2nd Floor Lake Zurich, IL 60047 USA 847-550-7909 847-550-2960 cheryl.roscher@fresenius-kabi.com

Device Trade Name:
Aurora Xi Plasmapheresis System
Aurora Xi system
Aurora Xi Software Version 1.2
Aurora Xi

Common Name/Usual Name:
Automated Blood Cell Separator (Filtration Separation Principle)

Classification Name:

21 CFR 864.9245 Automated Blood Cell Separator

Automated blood cell separator devices operating by centrifugal or filtration separation principle have been classified by the Center for Biologics Evaluation and Research as Class II devices with Special Controls (Docket 2005N-0017, Final Rule, 30-Nov-07).

Product Code and Classification Panel:
81 GKT (Hematology panel) - Separator, Automated, Apheresis

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:
Fresenius Kabi is claiming substantial equivalence with Aurora Xi Plasmapheresis System with Software Version 1.1, cleared under 510(k) BK170057 on August 25, 2017.

Device Description:
The Aurora Xi Plasmapheresis System, comprising the Aurora Xi instrument (hardware and software) and a PLASMACELL Xi disposable set, is an automated plasmapheresis system intended for routine collection of plasma to be processed as Source Plasma. The Aurora Xi system uses a rapidly rotating separator (membrane filter) to separate whole blood into plasma for collection and concentrated cells for reinfusion to the donor.

The collection of plasma by the Aurora Xi system is a fully automated procedure with the donor connected to the PLASMACELL Xi disposable set throughout the collection process.

The collection procedure requires a single venipuncture, which means that one access site is used to draw whole blood and return concentrated cellular components. Because of this, the procedure involves sequential cycles of alternating phases, one in which blood is drawn and plasma is separated and collected, and the other in which residual cellular components are returned. Venous pressure is continuously monitored to avoid exceeding the flow capacity of the donor's vein and to maintain comfortable pressures in the donor's vein.

The Touch Screen enables the operator to control the procedure, gather status information, and handle error conditions. Instrument safety systems and alert/alarm functions help ensure donor and operator safety.

Software Version 1.2 continues to provide bi-directional communication and data management capabilities for the Aurora Xi Plasmapheresis System.

Modification to the Existing Device:
Software Version 1.2 has been developed to provide customers the flexibility to configure their nomograms based on Collection Volume or Plasma Volume. Additionally, this version allows the operator to transition from collection to reinfusion or reinfusion to collection. Software Version 1.2 also includes minor enhancements and anomaly fixes.

New revisions of the Aurora Xi Plasmapheresis System Operator's Manual and Administrator's Guide have been created to include information relevant to Software Version 1.2. These have been updated to reflect the new functionality and minor enhancements added as a result of the new software version.

A summary comparison is presented below:

	Predicate Aurora Xi Software Version 1.1 (BK170057)	**Proposed Aurora Xi Software Version 1.2**
Manufacturer	Fresenius Kabi AG	Same
Trade Name	Aurora Xi Plasmapheresis System	Same
Common Name	Automated Blood Cell Separator	Same
Classification Name	Separator, Automated, Blood Cell, Diagnostic	Same
Regulation Number	21CFR 864.9245	Same
Product Code	GKT	Same
Device Class	II	Same
Indications for Use	The Aurora Xi Plasmapheresis System is intended for the automated collection of plasma by membrane filtration to be processed as Source Plasma. The Aurora Xi system is to be used with a single-use PLASMACELL Xi disposable set and 4% sodium citrate anticoagulant and allows for Saline and No Saline Protocol options.	Same
Separation Technology	Membrane filtration	Same
Performance	As listed in device labeling and finished product release specifications Nomogram based on Collection Volume Allows operator to transition from collection to final reinfusion phase	Same Nomogram based on Collection Volume or Plasma Volume Same; Additionally, allows operator to transition from collection to reinfusion or reinfusion to collection

Disposable Set	Single needle PLASMACELL Xi disposable set	Same
Graphic User Interface	Touch Screen graphical user interface	Same
Safety System	Monitors, detectors, sensors, alert/alarm system	Same
External Communication	Wired or Wireless	Same

Statement of Intended Use/Indications for Use:
The Aurora Xi Plasmapheresis System is intended for the automated collection of plasma by membrane filtration to be processed as Source Plasma. The Aurora Xi system is to be used with a single-use PLASMACELL Xi disposable set and 4% sodium citrate anticoagulant and allows for Saline and No Saline Protocol options.

Technological Characteristics as Compared to the Predicate Device
The technological characteristics of the Aurora Xi Plasmapheresis System with Software Version 1.2 remain the same as the predicate device. It is a microprocessor-controlled electromechanical device comprising pumps, clamps, monitors and sensors that move and direct donor blood through the PLASMACELL Xi disposable set. The plasma is collected, and the other components are returned to the donor.

Software Version 1.2, subject of this 510(k), does not change the operating principle of the Aurora Xi Plasmapheresis System.

Performance Data:
System verification and validation activities have been performed on the Aurora Xi system with Software Version 1.2, which verified that the modified Aurora Xi Plasmapheresis System performs as intended in a safe and effective manner that is substantially equivalent to the predicate device.

Conclusion:
Based on the verification and validation activities performed, the Aurora Xi Plasmapheresis System with Software Version 1.2 provides a device system that is substantially equivalent to the currently marketed Aurora Xi Plasmapheresis System.