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510(K) SUMMARY

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Device Trade Name:
Aurora Plasmapheresis System
Aurora system
Aurora Software Version 2.1
Aurora Software Version 2.1 Upgrade Kit (also known as “Aurora 2.1”)
Aurora

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 Plasmapheresis System with Software Version 1.3, cleared under 510(k) BK160012 on May 19, 2016.

Device Description:
The Aurora Plasmapheresis System, comprising the Aurora instrument (hardware and software) and a PLASMACELL-C disposable set, is an automated plasmapheresis system intended for routine collection of blood plasma. The Aurora system achieves rapid separation of whole blood into concentrated cellular components and plasma by means of a spinning (i.e., rotating) membrane filter. The concentrated cellular components are returned to the donor and collected plasma is processed as Source Plasma.

The collection of plasma by the Aurora system is a fully automated procedure with the donor connected to the PLASMACELL-C disposable set throughout the collection process. Multiple safety systems and alarm functions are incorporated into the plasmapheresis system to ensure donor and operator safety.

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 operator uses the Aurora Touch Screen to control the procedure, gather important information on its status, and handle error conditions that may arise.

The Aurora system provides bi-directional communication and data management capabilities.

Modification to the Existing Device:
Software Version 2.1 has been developed to provide customers the flexibility to configure their nomograms based on Collection Volume or Plasma Volume. Software Version 2.1 also includes minor enhancements and anomaly fixes.

New revisions of the Aurora Plasmapheresis System Operator's Manual and Administrator's Guide have been created to include information relevant to Software Version 2.1. 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 Software Version 1.3 (BK160012)	**Proposed Aurora Software Version 2.1**
Manufacturer	Fresenius Kabi AG	Same
Trade Name	Aurora 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	81 GKT	Same
Device Class	II	Same
Separation Technology	Membrane filtration	Same
Performance	As listed in device labeling and finished product release specifications Nomogram based on Collection Volume	Same Nomogram based on Collection Volume or Plasma Volume
Disposable Set	Single needle PLASMACELL-C 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 Plasmapheresis system is an automated plasmapheresis system designed to collect plasma by membrane filtration using single-use disposable sets. Collected plasma is to be processed as Source Plasma.

Technological Characteristics as Compared to the Predicate Device
The technological characteristics of the Aurora Plasmapheresis System with Software Version 2.1 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-C disposable set. The plasma is collected, and the other components are returned to the donor.

Software Version 2.1, subject of this 510(k), does not change the operating principle of the Aurora Plasmapheresis System. None of the previous changes made, as described in Section 21, alone or as a whole, drive the need for a 510(k).

Performance Data:
System verification and validation activities have been performed on the Aurora system with Software Version 2.1, which verified that the modified Aurora 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 Plasmapheresis System with Software Version 2.1 provides a device system that is substantially equivalent to the currently marketed Aurora Plasmapheresis System.