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510(K) SUMMARY

Date Prepared:

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510(k) Owner and Contact Person:

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Device Trade Name:
Aurora Plasmapheresis System
Aurora System
Aurora Software Version 1.3 Upgrade Kit
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 the currently cleared version of the Aurora Plasmapheresis System. The Aurora System was cleared under 510(k) BK110072 on March 29, 2012.

Device Description:
The Aurora Plasmapheresis System, comprised of 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 a rapid separation of whole blood into concentrated cellular components and virtually cell-free plasma by means of a spinning (i.e., rotating) membrane filter. The concentrated cellular components are returned to the donor and collected plasma can be 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.

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

Modification to the Existing Device:
Software version 1.3 has been developed for use with the Aurora Plasmapheresis System. This updated software provides new functionality for automated intra-procedure saline infusion along with other minor software updates.

New revisions of the Aurora Plasmapheresis System Operator's Manual and Administrator's Guide have been created to include information relevant to Software Version 1.3. These have been updated to reflect the new functionality and minor enhancements added as a result of the new software version.

The modified software will be incorporated into newly manufactured Aurora instruments after 510(k) clearance in the US. In addition, it can be distributed as part of an upgrade kit to allow software upgrades to existing Aurora instruments in the installed base.

Statement of Intended Use/Indications for Use:

The Aurora Plasmapheresis System is an automated plasmapheresis system designed to collect virtually cell-free 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 remain the same as the currently cleared device. It is a microprocessor-controlled electromechanical device comprised of 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 1.3, subject of this 510(k), does not change the operating principle of the Aurora Plasmapheresis System. The data management capabilities remain the same as the cleared Aurora device. 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:

Software verification, system verification, and system validation were performed in support of this submission. The results of the testing were acceptable.

Conclusion:

Based on the verification and validation activities performed, the Aurora Plasmapheresis System modified with Software Version 1.3 provides a device system that is substantially equivalent to the currently marketed Aurora System.