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510(K) SUMMARY

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Device Trade Name:
"Aurora Xi Plasmapheresis System" can also be called "Aurora Xi" or the "Aurora Xi system".

"PLASMACELL Xi disposable set" can also be called "PLASMACELL Xi set" or "PLASMACELL 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 the cleared Aurora Plasmapheresis System. The Aurora system was cleared under 510(k) BK110072 on March 29, 2012.

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 virtually cell-free plasma to be processed as Source Plasma. The Aurora Xi system, like the predicate Aurora 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.

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.

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 remain the same as the cleared 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.

Performance Data:

System validation and verification activities have been performed on the Aurora Xi system, which verified that the Aurora Xi Plasmapheresis System performs as intended in a safe and effective manner that is substantially equivalent to the Aurora Plasmapheresis System.

Clinical evaluation demonstrated the safety and efficacy of plasma collection using the Aurora Xi Plasmapheresis System. The primary efficacy parameter demonstrated that the Aurora Xi system is non-inferior to Aurora system for Factor VIIIc activity level after freezing and thawing. Plasma collection procedures were safely completed using the Aurora Xi Plasmapheresis System. All adverse effects are unrelated to the study device and are commonly encountered during routine blood donation and apheresis procedures.

Conclusion:

Based on the verification and validation activities and clinical evaluation, the Aurora Xi Plasmapheresis System provides a system that is substantially equivalent to the predicate Aurora Plasmapheresis System.