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510(k) SUMMARY

Date Prepared

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Owner/Operator

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Device Trade Name

Aurora Xi Plasmapheresis System
Aurora Xi system
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).

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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 Version 1.2, cleared under 510(k) BK180268 on November 2, 2018.

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 requiring 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.

The Aurora Xi Plasmapheresis System continues to provide bi-directional communication and data management capabilities.

Statement of Intended 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 Comparison as Compared to the Predicate Device

The technological characteristics of the Aurora Xi Plasmapheresis System 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.

The instrument modification and labeling changes, subject of this 510(k), do not change the operating principle of the Aurora Xi Plasmapheresis System.

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Modification to the Existing Device

The tubing guides on the Aurora Xi instrument have been modified to help improve system safety, and the Operator's Manual was updated accordingly.

Performance Data

System verification and validation activities have been performed on the Aurora Xi system with modified tubing guides, 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 modified tubing guides continues to provide a device that is substantially equivalent to the predicate device.