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510(k) Summary

Contact Details

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Device Name

Device Trade Name	Aurora Xi Plasmapheresis System Software Version 2.0
Common Name	Automated Blood Cell Separator
Classification Name	Separator, Automated, Blood Cell, Diagnostic
Regulation Number	864.9245
Product Code	GKT

Legally Marketed Predicate Devices

Predicate 510(k) Number	BK220788
Predicate Trade Name	Aurora Xi Plasmapheresis System

Product Code GKT

Device Description Summary

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 Source Plasma collection. Whole blood is drawn from the donor and plasma is separated from concentrated cells using a rapidly rotating separator (membrane filter). The plasma is collected in a collection container and residual cellular components are then returned to the donor. This draw and return cycle is repeated until the target plasma collection volume is reached.

Aurora Xi Software Version 2.0 includes an alternate, linear nomogram that uses donor characteristics to target a collection volume of up to 1098 mL of plasma product (up to 1000 mL pure plasma) per donation, in addition to existing cleared nomograms that target a collection volume of up to 880-911 mL of plasma product (up to 800 mL pure plasma) per donation.

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.

Indications for Use Comparison

The indications for use is same as predicate device.

Technological Comparison

The Aurora Xi with Software Version 2.0 has the same technology characteristics, operational principle, separation technology, safety principle and operation system as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Aurora Xi Plasmapheresis System Software Version 2.0 was verified and validated at both software and system levels. Non-clinical testing demonstrated that the modified device performed as intended in a safe and effective manner that is substantially equivalent to the predicate device.

A multicenter, prospective randomized controlled clinical trial was conducted to evaluate the new nomogram in software version 2.0 compared to the existing nomogram in the predicate device.

The primary objective of this study was to demonstrate that the overall rate of significant hypotensive adverse events (SHAEs, IQPP DAE Classification 1.2-1.6) in donors using the Aurora Xi new nomogram algorithm was less than double the SHAE rate in donors using the existing cleared nomogram algorithm. Clinical data demonstrated that the study met the primary endpoint and that the Aurora Xi system with the new nomogram is substantially equivalent to the predicate device.

Based on the non-clinical and clinical activities performed, the Aurora Xi Plasmapheresis System with Software Version 2.0 provides a device system that is substantially equivalent to the predicate device.