510(k) SUMMARY

Date Prepared:

December 1st, 2011

Owner and Contact Person:

Owner/Operator	Owner/Operator #: 9098803 Fenwal, Inc. Three Corporate Drive Lake Zurich, IL 60047
Contact Name: Title: Address: Telephone: Fax: E-mail:	Kristen Bozzelli Specialist, Regulatory Affairs Three Corporate Drive Lake Zurich, IL 60047 847-550-7927 847-550-2960 kristen.bozzelli@fenwalinc.com

Device Name(s):

Aurora Plasmapheresis System

Common 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).

Classification Panel:

81 GKT (Hematology panel)- Separator, Automated, Apheresis

Legally Marketed Device under Which Substantial Equivalence is Being Claimed:

Fenwal, Inc. is claiming substantial equivalence of the Aurora Plasmapheresis System with the currently marketed version of the Autopheresis-C Plasmapheresis System, along with its additional operating protocols, software updates and disposables changes reported in PMA Supplements, PMA Annual Reports, which was approved to market under PMA BP850001 on March 24, 1986 and subsequently down-classified to Class II and cleared most recently under BK100050.

Device Description

The Aurora Plasmapheresis System is an automated plasmapheresis system comprised of the Aurora Plasmapheresis Instrument and the Plasmacell-C disposable set. As in the original Autopheresis-C Plasmapheresis System, the Aurora system achieves a rapid, but gentle separation of whole blood into concentrated cellular components and virtually cell-free plasma by means of a rotating membrane filter. The concentrated cellular components are reinfused back to the donor and plasma is collected for processing as Source Plasma.

The collection of plasma by the Aurora Plasmapheresis system is a fully automated procedure with the donor connected to the 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 plasma is separated and collected, and the other in which residual cellular components are reinfused. Venous pressure is monitored to assure pressure does not exceed the flow capacity of the donor's vein.

A touchscreen with a graphical user interface displays messages and allows the operator to control the procedure, gather important information on its status and handle error conditions that may arise. The Aurora Instrument also has a discrete "Stop" push button not associated with the touchscreen to provide the ability for the operator to stop a procedure at any time to protect donor safety. An LED light on the top of the instrument housing displays three colors to indicate the status of the machine with corresponding audio feedback as appropriate.

The Aurora Instrument can accept barcode data scanned by the operator using the included bar code scanner.

The Aurora Instrument can interface with DXT Relay, a Microsoft Windows-based software application intended to be used by trained blood center professionals to receive and transmit data between blood bank instruments (apheresis and non-apheresis) and Computer Systems. The Aurora Instrument is

capable of wireless and wired data transfer. DXT Relay creates CFR Part 11-capable records which can be used by CFR Part 11-compliant electronic data management systems.

Statement of Intended 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 Aurora Plasmapheresis System is a line extension of the Autopheresis-C System. The Aurora Instrument replaces the Autopheresis-C instrument's one-line text display and keypad with a touch screen and graphical user interface based on the interface used in the currently marketed ALYX Apheresis System. Wireless, Ethernet, and USB capability is integrated into the instrument. Some hardware components have been updated.

The Aurora 1.0 Software is based on the Autopheresis-C 6.22 software. Functionality is added to accommodate the hardware modifications, including integral data communication capability. The included bar code scanner can be used to enter procedure data. Aurora Software is designed to be compatible with DXT Relay Software, which receives and transmits data between blood bank instruments and computer systems. When connected to DXT Relay, the Aurora system can create procedure records that are CFR 21 Part II capable, which can be used by CFR Part 11-compliant electronic data management systems.

All other technological characteristics of the Aurora Plasmapheresis System remain the same as the currently marketed Autopheresis-C System. It is a continuous flow filtration separation device that uses the currently marketed Plasmacell-C disposable set.

Performance Data:
Testing has been conducted to verify the safety and performance of the Aurora Plasmapheresis System. EMC, Electrical Safety, Verification, Validation, and Coexistence testing were completed successfully.

Conclusions:

Based on the design and development activities performed for the Aurora Plasmapheresis System, the Aurora Plasmapheresis System is substantially equivalent to the Autopheresis-C Plasmapheresis System.