BK020059

510(k) Summary of Safety and Effectiveness

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Date of Summary:	November 14, 2002
Trade/Proprietary Name of Device:	ALYX Component Collection System
Common/Usual Name of Device:	Automated Centrifugal Blood Cell Separator
Classification Name of Device:	Automated Blood Cell Separator (21 CFR 864.9245)
Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:	Haemonetics PCS2 (BK840021)
Device Description:	The ALYX apheresis instrument and disposable apheresis kit constitute a system for centrifugal blood separation. It is intended for use in blood collection establishments for the collection of Sodium Citrate-anticoagulated Plasma. The instrument has pumps, clamps and valves that move donor blood through the disposable kit. The Plasma is collected with Sodium Citrate anticoagulant and the cellular components are returned to the donor with 0.9% Sodium Chloride, USP. The plasma is frozen within eight (8) hours of collection at -30° C and may by processed as Source Plasma.

Intended Use of the Device:	The ALYX apheresis system is intended for use in blood collection establishments to collect and separate whole blood into its components.
Comparison of Technological Characteristics of the Device vs. the Legally Marketed Device:	The function of the ALYX apheresis system is similar to that of other legally marketed devices such as the Haemonetics PCS2 and other commercially available centrifugal-based blood cell separators. The ALYX system utilizes an apheresis kit that incorporates tubing, a donor needle, a centrifuge chamber and blood product containers manufactured from PVC.
Brief Discussion of Nonclinical and Clinical Tests and Their Results Submitted in the Application:	A clinical study was performed to evaluate the ALYX system for the collection of Plasma Only. The randomized, cross-over study compared plasma procedures and collected plasma products between the ALYX system and the Haemonetics PCS2. Donor subjects participated in 22 completed ALYX plasma procedures that were paired with 22 Haemonetics procedures.
Conclusion Drawn from the Nonclinical and Clinical Tests that Demonstrate that the Device is Safe, Effective, and Performs As Well As or Better Than the Legally Marketed Device:	The results of this study demonstrated that subject safety was maintained during the plasma collection procedures. Subject pre- and post-procedure vital signs and hematological parameters were within clinically acceptable limits. Data from the study demonstrate the ALYX system successfully achieves collection of Sodium Citrate-anticoagulated plasma from a single subject. All testing parameters were within normal limits and are in compliance with current regulatory standards for plasma products.