BK020056

510(k) Summary of Safety and Effectiveness

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Date of Summary:	November 13, 2002
Trade/Proprietary Name of Device:	ALYX 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 MCS+ (BK960095) COBE Trima (BK990025)
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 concurrent collection of two units of Red Blood Cells (2RBC). The instrument has pumps, clamps and valves that move donor blood through the disposable kit. The Red Blood Cells are collected with ACD-A anticoagulant and the remaining components are returned to the donor with 0.9% Sodium Chloride, USP. After addition of ——— Red Cell Preservation solution the Red Blood Cells may be stored for 42 days. Leukoreduction of the collected Red Cell product occurs immediately post-collection by the ——————— leukoreduction filter.
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.

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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 MCS+, the COBE Trima and other commercially available centrifugal-based blood cell separators. The ALYX system utilizes a closed system apheresis kit that incorporates processing solutions, tubing, a donor needle, a centrifuge chamber and blood product containers made from PVC.
Brief Discussion of Nonclinical and Clinical Tests and Their Results Submitted in the Application:	An initial clinical study was performed to evaluate the ALYX system for the concurrent collection of two units of Red Blood Cells. The study consisted of collection of two units of Red Blood Cells from 121 donors – 10 donors were female, 111 donors were male. 91 units were leukoreduced and stored for 42 days. 30 units were not leukoreduced and were stored for 42 days. In Vivo recovery studies were performed on 37 units. Studies were not performed to support gamma irradiation or freezing of Red Cells collected by the ALYX system. Additional studies performed on female donors of two units of Red Blood Cells within the weight range of 150 – 174 pounds demonstrated subject safety with minimal effects.
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 the initial clinical study combined with those of this current study demonstrate that subject safety is maintained during the 2RBC procedures on the ALYX system. No adverse reactions beyond those that may typically be experienced in an automated apheresis procedure occurred during the initial and additional procedures. None of the adverse events reported were considered related to the device. All additional female subjects participating in a seven (7) day follow-up questionnaire stated that there was minimal disruption of their normal activities. The data demonstrate that collection of two units of Red Blood Cells with the ALYX system is safe for qualifying donors.

for Anne Wallace

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