BK010033

Baxter

510(k) Summary of Safety and Effectiveness

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Date Summary Prepared:	August 28, 2001
Trade/Proprietary Name of Device:	Automated 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 MCS+ (BK960095) COBE Trima (BK990025) Baxter Home Choice (K923065)
Device Description:	The Automated Component Collection system (ACC) 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 and the remaining components are returned to the donor with 0.9% Sodium Chloride, USP. The Red Blood Cells may be stored for 42 days either with or without leukoreduction.
Intended Use of the Device:	The Automated Component Collection system is intended for use in blood collection establishments to collect and separate whole blood into its components.
Comparison of Technological	The function of the ACC system is similar to that of other legally marketed devices such as the Haemonetics

Characteristics of the Device vs. the Legally Marketed Device:	MCS+, the COBE Trima and other commercially available centrifugal-based blood cell separators. The ACC 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:	A clinical study was performed to evaluate the ACC system for the concurrent collection two units of Red Blood Cells. The study consisted of collection of two units of Red Blood Cells from 121 donors. 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.
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 2RBC procedures. Subject pre- and post-procedure vital signs and hematological parameters were within clinically acceptable limits. Data from the study also demonstrate the system successfully produces collection of two units of Red Blood Cells from a single subject. Leukocyte reduced products meet or exceed current FDA standards for leukoreduction. Day 42 storage data for leukoreduced and non-leukoreduced Red Blood Cell products demonstrates that all testing parameters were within normal limits and are in compliance with current regulatory standards for Red Blood Cells.