510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: BK040057

Date of Application:	June 18, 2004		
Applicant:	Immucor, Inc.		
Address:	3130 Gateway Drive Norcross, Georgia 30071		
Establishment Registration Number:	1034569		
Contact Person:	J. Scott Webber Vice President World Wide Regulatory Affairs		
Telephone:	(770) 441-2051		
FAX:	(770) 242-8930		
Trade Name:	Checkcell® (Weak)		
Common Name:	IgG-coated Red Blood Cells		
Classification:	Class II		
Classification Name:	Quality control kits for blood bank reagents		
Product Code:	KSF		
Substantial Equivalence:	Checkcell® (Weak) is functionally equivalent to the current legally marketed Coombs Control Cells (EIgG Weak) previously reviewed by CBER under BK960056, dated 10/23/1996.		
Device Description: Intended Use:	Checkcell® (Weak) is intended to confirm the validity of negative antiglobulin tests obtained with Anti-Human Globulin that contains an anti-IgG component.		
Summary of technological characteristics of new device compared to the predicate device:		**Predicate *Coombs Control Cells (EIgG Weak) BK960056***	**New *Checkcell® (Weak)***
	Device consists of IgG-coated red blood cells in a buffered preservative solution.	X	X
	Device is for use in similar testing applications	X	X

	Non-clinical Testing	Predicate *Coombs Control Cells (EIgG Weak) BK960056*	New *Checkcell® (Weak)*
Brief discussion of the non-clinical tests and how their results support a determination of substantial equivalence:	Potency (AHG Titer)	64	32
	Reactivity when added to negative Indirect Antiglobulin Tests	$2+^{s}$	2+
	Reactivity in Direct Antiglobulin Tests	$2+^{s}$	$2+^{s}$
	These data demonstrate that the performance of Checkcell® (Weak) is substantially equivalent to the performance of Coombs Control Cells (EIgG Weak).		
Conclusions:	Checkcell® (Weak) is substantially equivalent to the currently marketed device, Coombs Control Cells (EIgG Weak).		