5. 510(k) SUMMARY

Applicant Information:

Date Prepared:	March 16, 2007
Applicant:	Immucor, Inc.
Address:	3130 Gateway Drive
	Norcross, Georgia 30071
U.S. License No.:	886

Contact Person: J. Scott Webber
Vice President World Wide Regulatory Affairs
Telephone: (770) 441-2051
FAX: (770) 242-8930

Device Information:

Device Name:	Monoclonal Control
Common Name:	Quality Control for Routine Blood Bank Reagents
Classification:	21 CFR 864.9650, Class II (BK040010)
Classification Name:	Quality Control for Blood Banking Reagents / KSF

Predicate Devices:
Immucor Monoclonal Control (BK040010) dated 4/23/2004

Device Description and Intended Use:
Immucor Monoclonal Control is a phosphate buffered saline solution which contains glycine, EDTA, bovine albumin, gelatin and sodium azide in concentrations similar to that found in Immucor Monoclonal Rh blood grouping reagents and Gamma-clone blood grouping reagents.

It is intended to be used as a control for Immucor low protein Blood Grouping Reagents and Gamma-clone blood grouping reagents used in Slide, Tube, and Microplate Tests.

Comparison to Predicate Device(s):
A comparison between the new Monoclonal Control and the predicate (current) device is presented in the table below. The devices are compared based on intended use, material and shelf-life.

Intended Use	Monoclonal Control (Predicate)	Monoclonal Control (New)	Gamma-clone Control (Predicate)
Used as a negative control in Slide, Tube and Microplate tests for Immucor low protein blood grouping reagents.	X	X	
Used as a negative control in Slide, Tube and Microplate tests for Gamma-clone blood grouping reagents.		X	X
Material			
A phosphate buffered saline solution which contains glycine, EDTA, bovine albumin, gelatin and sodium azide in concentrations similar to that of Immucor, Inc. low protein monoclonal blood grouping reagents.	X	X	
Phosphate buffered saline solution which contains glycine, EDTA, bovine albumin, gelatin, sodium azide in concentrations similar to that of Gamma-clone blood grouping reagents.		X	X
Shelf-life			
24-month expiration dating period	X	X	X

Comparison Discussion

Intended Use: The intended use will be extended to include use with Gamma-clone blood grouping reagents. The new device uses the same test methodologies and procedures as the current device.

Materials (Formulation): There are no changes to the manufacturing process or formulation of the device.

Shelf-life: Monoclonal Control will continue to be labeled with the same 24-month expiration dating period. This is the same expiration dating period as Immucor's monoclonal blood group reagents. Monoclonal Control does not contain an active material.

Summary of Bench Testing

Non-clinical studies were performed to support the additional intended use and performance of the new Monoclonal Control. Validation studies were performed to determine whether the new Monoclonal Control is as effective as Gamma-clone control as a negative control for Gamma-clone blood grouping reagents.

Comparison of reactivity studies of Monoclonal Control and Gamma-clone Control reagents were performed with DAT positive red cell suspensions. Monoclonal Control and Gamma-clone control reagents demonstrated no differences in their reactivity with sensitized red blood cells. Both control reagents showed negative reactivity with all red blood samples, verifying that the positive results obtained with the blood grouping reagents are specific. This result demonstrates that the Monoclonal Control Reagent and Gamma-clone Control are comparable and that they can be used as control reagents for currently available monoclonal blood grouping reagents from ImmucorGamma.

Summary of Clinical Tests

The Monoclonal Control was used as a sample control to verify the validity of test reactions with Gamma-clone and Immucor blood grouping reagents in hemagglutination assays on the Galileo Echo. The Monoclonal Control demonstrated the expected negative reaction on the Galileo Echo. Positive and equivocal reactions were due to debris in the well and not a reagent failure.

Monoclonal tests results by manual tube method were compared to Gamma-clone Control test results (tube method) to demonstrate the effectiveness of using the Monoclonal Control reagent with Gamma-clone blood grouping reagents. There was 100% agreement between Monoclonal Control and Gamma-clone Control by manual tube method. No positive reactions were detected in the performance of direct hemagglutination reactions by manual tube method with the Monoclonal or Gamma-clone Controls.

In conclusion, this study demonstrates that the new Monoclonal Control is substantially equivalent to the predicate devices and supports its new intended use as a negative control for Gamma-clone blood grouping reagents.