5. 510(k) SUMMARY

Applicant Information:

Date Prepared:	March 16, 2007
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Device Information:

Device Name:	WB corQC™
Common Name:	Daily Quality Control System for Routine Blood Bank Reagents
Classification:	21 CFR 864.9650, Class II
Classification Name:	Kit, Quality Control for Blood Banking Reagents / KSF

Predicate Devices:
Immucor corQC Test System (BK060016), 5/9/2006

Device Description and Intended Use
Immucor WB corQC is prepared from red blood cells collected from human blood donors. Each individual donation contains the appropriate ABO, Rh and Kell blood group antigens. A set of WB corQC is composed of four tubes of varying antigenic and antibody makeup (listed below). Each packaging of the product contains a pair of each of the four tubes:

Cell 1: A Rh (D) Pos, C+c-E-e+K+ red blood cells containing anti-B and anti-c in diluent
Cell 2: B Rh (D) Neg, C-c+E-e+K- red blood cells containing anti-A and anti-D in diluent
Cell 3: O Rh (D) Neg, C-c+E=e-K- red blood cells containing anti-A and anti B in diluent
Cell 4: O Rh (D) Pos, C+c+E+e+K- red blood cells containing anti-A and anti-B in diluent

WB corQC reagent red blood cells have been prepared as a 17-23% suspension in a buffered preservative solution containing adenosine and adenine to retard hemolysis and loss of antigenicity during the dating period. Chloramphenicol, neomycin sulfate and gentamycin sulfate are added as preservatives.

WB corQC is used for the daily quality control evaluation of routine blood bank reagents. It is used to evaluate the performance of Anti-A, Anti-B, Anti-A,B, Anti-D and Rh control material, serum (reverse) grouping reagent red blood cells, Capture solid phase antibody screening reagents and Rh and Kell phenotyping reagents, by automated methods. WB corQC should produce visible reactions with reagents where positive results are expected, and negative results where no reaction is expected. Falsely negative or falsely positive test results with WB corQC indicate reagent deterioration, reagent contamination, or suboptimal performance of test equipment.

Comparison to Predicate Device(s):

A comparison between WB corQC and its predicate device, corQC Test System (BK060016) is presented in the table below. The predicate device is comprised of corQC Reagent Cells and corQC Antiserum. WB corQC is comprised of reagent red blood cells only. The devices are compared based on intended use and material.

Intended Use	corQC Reagent Cells	WB corQC (New)
Daily quality control reagents used to evaluate the reactivity of routine blood bank reagents.	X	X
Used in manual test methods performed in settings such as blood banks, transfusion services, and clinical laboratories.	X	
Used in automated test methods performed in settings such as blood banks, transfusion services, and clinical laboratories.		X
Material		
Reagent cells: group AB, D+ red blood cells prepared as a 2-4% suspension in a buffered preservative solution.	X	
Reagent cells: red blood cells containing ABO, Rh and Kell blood group antigens prepared as a 17-23% suspension in a buffered preservative solution		X

Comparison Discussion

Intended Use: Both the new device and the predicate are intended for daily quality control of blood bank reagents. There are no changes to the intended use of the device. The new device uses the same test methodology as the current device.

Materials (Formulation): The new device is manufactured according to similar manufacturing procedures as the predicate device.

Summary of Bench Testing

Verification studies were performed to evaluate the new WB corQC for its fulfillment of intended use requirements. The performance of three individual lots of product was evaluated. Each lot was placed into three separate product groups: Intended Use, In-Use, and temperature excursion (37°C) group.

The methods of use included manual hemagglutination testing by tube technique and red cell adherence assays performed on the Echo automated instrument. Real time and in-use stability of the product was assessed by hemolysis, potency, and reactivity assays.

Manual Testing was performed to investigate hemolysis, reactivity, potency and specificity of the WB corQC cells within each product group mentioned above. All samples (except temperature excursion samples) passed acceptance criteria for initial and 45 day testing.

WB corQC samples were tested on the Echo automated instrument for all assays requiring daily QC. These assays include forward and reverse grouping, antibody screen, Weak D testing, phenotype testing. All WB corQC cells (except temperature excursion samples) met the acceptance criteria for these assays.

Summary of Clinical Tests

Daily QC on the Galileo Echo instrument with WB corQC samples was performed as required for the Group, Screen, Group Screen, Ag_CcEeK and Weak D Assays. A total of 561 batches were processed and 42 (7.5%) batches demonstrated invalid test results. The results for the 42 batches were reviewed and the batches were correctly invalidated by the instrument software. The use of the WB corQC identified operator errors (reagent contamination, improper reagent preparation) and potential reagent problems. The WB corQC reagents provide effective controls for reagents used for the determination of ABO/Rh blood type, Rh and K blood type, Weak D and antibody detection.

In conclusion, these studies demonstrate that the new WB corQC is substantially equivalent to the predicate device for the daily quality control of routine blood bank reagents.