BK020063

SECTION 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

LeukoSure™ Enumeration Kit
with
Leuko-Trol™ RBC Control Cells and Leuko-Trol™ Platelet Control Cells

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2.0 DATE SUBMITTED: November 22, 2002

3.0 DEVICE NAME:

3.1 Proprietary Name:
LeukoSure™ Enumeration Kit *with* Leuko-Trol™ RBC Control Cells and Leuko-Trol™ Platelet Control Cells

3.2 Common or Usual or Classification Name:
Quality Control Kit for Blood Banking Reagents *with* Hematology Quality Control Mixtures

3.3 Product Classification:
Product Code: KSF, 21 CFR 864.9650, Device Class: II; JPK, 21 CFR 864.8625, Device Class: II

4.0 PREDICATE DEVICE:
BK970046 – BD LeucoCOUNT™ Kit (Mfr: BD Biosciences)
BK000035 - R&D LeukoReduced RBC™ Control (Mfr: R & D Systems, Inc.)
BK000036 - R&D LeukoReduced Plt™ Control (Mfr: R & D Systems, Inc.)

5.0 DESCRIPTION OF DEVICE:
The *LeukoSure™ Enumeration Kit with Leuko-Trol™ RBC Control Cells and Leuko-Trol™ Platelet Control Cells*, is a new set of products for the enumeration of residual leukocytes (rWBC) in leuko-reduced red blood cell (RBC) and platelet products by flow cytometry. The *LeukoSure™ Enumeration Kit* is comprised of a set of reagents [LeukoSure™ Lyse Reagent, LeukoSure™ Stain Reagent, LeukoSure™ Fluorospheres] used to prepare and enumerate white blood cells. The *Leuko-Trol™ RBC Control Cells* [Low, High] and the *Leuko-Trol™ Platelet Control Cells* [Low, High] are used as complete process controls to monitor leukoreduced red blood cell products and platelet products, respectively, including the dilution and staining process, method set-up and white blood cell (WBC) enumeration.

6.0 INTENDED USE OF DEVICE:
The *LeukoSure™ Enumeration Kit with Leuko-Trol™ RBC Control Cells and Leuko-Trol™ Platelet Control Cells*, is intended "For In Vitro Diagnostic Use."

7.0 COMPARISON TO PREDICATE:
The *LeukoSure™ Enumeration Kit, Leuko-Trol™ RBC Control Cells* and *Leuko-Trol™ Platelet Control Cells* are substantially equivalent to the "For In Vitro Diagnostic Use" products: BD LeucoCOUNT™ Kit, R&D LeukoReduced RBC™ Control and R&D LeukoReduced Plt™ Control. These products have the same intended uses, measure the same sample types, and demonstrate comparable performance characteristics. These products are also governed by the same regulations, and employ the same features, principles of operation and techniques for cell identification and enumeration. This includes the nucleic acid dye, propidium iodide, to stain rWBC; a lysing and permeabilizing reagent to allow entry of propidium iodide; a reagent for direct absolute count determination; two-level assayed quality control reagents for monitoring the leukoreduced RBC and platelet products; flow cytometry system with basic instrument set-up software and reagents; and the ability to count rWBC in red blood cell and platelet products as WBC/µL.

8.0 SUMMARY OF PERFORMANCE DATA:

8.1 LINEARITY:
Replicate measurements were made at each of 10 serial dilutions for WBC-spiked RBC and platelet samples to achieve a dynamic range (0 to 400 cells/µL) and a low-end sensitivity range (0 to 20 cells/µL). Samples were prepared according to the LeukoSure™ Enumeration Kit package insert and analyzed on COULTER® EPICS® XL™/XL-MCL™ and Cytomics FC Series flow cytometers. Values were expressed in terms of absolute count (cells/µL). The slopes of the regression lines provided with the plots for WBC absolute counts showed the mathematical measure of linearity. This was supported by minimal potential

assay bias as evidenced by the y-intercepts for the analyses. Expected absolute counts demonstrated high correlation with the recovered absolute counts for the dynamic range and low-end sensitivity for WBC spiked RBC and platelet samples on both flow cytometers.

8.2 ACCURACY OF METHOD:

The degree of accuracy of the WBC absolute counts obtained in both leukoreduced RBC and platelet samples was evaluated by comparing the LeukoSure™ Enumeration Kit to the BD LeucoCOUNT™ Kit at three evaluation sites. Leukoreduced RBC products and platelet products were prepared according to each manufacturer's instructions and analyzed on the COULTER® EPICS® XL™/XL-MCL™ and Cytomics FC Series flow cytometers using the LeukoSure™ Enumeration Kit, and on a BD FACS™ Brand flow cytometer using the BD LeucoCOUNT™ Kit. Results analyzed in terms of minimums, maximums, means ± SD, CVs, confidence intervals and regression analyses demonstrated all results passed acceptance criteria.

8.3 PRECISION (Interlaboratory and Intralaboratory Precision):

Studies were performed on the same day using three flow cytometers: COULTER® EPICS® XL™/XL-MCL™, Cytomics FC Series, and BD FACSCalibur™. Four specimens spanning the dynamic range (0 to 400 WBC/µL) were prepared for both RBC and platelet samples. These specimens were split into three aliquots; one aliquot of each level was used to prepare the samples (n = 10) for each flow cytometer. Values were expressed in terms of absolute counts (WBC/µL). Results were analyzed in terms of means ± SD for the sample types, levels and instruments. The values for the replicate measurements showed little variation between the instruments and within sample type and level. These data demonstrate the assay precision and reproducibility of the LeukoSure™ Enumeration Kit.

8.4 STABILITY:

- Sample stability was evaluated by comparing samples stained and acquired within 1 hour of leukoreduction to samples stained and acquired at 24 or 48 hours after leukoreduction and analyzed within 2 hours.
- Stained sample stability was determined by comparing samples stained and acquired within 1 hour of leukoreduction to samples stained at 24 hours and analyzed after an additional 24 hours of storage.
- Prior to staining, RBC products were refrigerated (2-8°C) and platelet concentrates were kept at room temperature (20-25°C).

The results obtained showed that RBC and platelet samples may be stained up to 48 hours after leukoreduction. Samples stained within 24 hours of leukoreduction may be refrigerated and run up to 24 hours later.

8.5 FLOW CYTOMETER COMPARISON:

The performance of the LeukoSure™ Enumeration Kit was evaluated on COULTER™ EPICS® XL™/XL-MCL™, Cytomics FC Series, and BD FACS™ Brand flow cytometers. The results from the regression analysis on 30 RBC and 30 platelet samples showed the XL™/XL-MCL vs. FACS™ Brand, and the FC Series vs. FACS™ Brand, flow cytometers produced comparable WBC absolute counts across the dynamic range of the LeukoSure™ Enumeration Kit assay.

Comparison of LeukoSure™ Enumeration Kit on COULTER® EPICS® XL™/XL-MCL™ vs. BD FACS™ Brand, and Cytomics FC 500 Series vs. BD FACS™ Brand Flow Cytometers

Instrument and Sample Type	n	Slope	Intercept	Correlation
COULTER® EPICS® XL™/XL-MCL™ vs. BD FACS™ Brand				
RBC	30	0.9856	–0.2008	0.9924
Platelets	30	1.0281	0.2681	0.9906
Cytomics FC 500 Series vs. BD FACS™ Brand				
RBC	30	1.0485	–0.0963	0.9900
Platelets	30	0.9967	0.0187	0.9833

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS:

This document is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.