A. 510(k) Summary

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: BK000046.

SUBMITTER:
BioErgonomics, Inc.
St. Paul, MN 55127
Phone: 651-426-6466
Fax: 651-426-5740

CONTACT PERSON:
Carol A. Buchert
Vice President of Manufacturing and Production

DATE PREPARED:
September 29, 2000

TRADE NAME:
FluoroTrol™ -rWBC/RBC Bi-Level Control Kit
FluoroTrol™ -rWBC/PRP Bi-Level Control Kit

COMMON NAME:
White Cell Control

CLASSIFICATION:
Class II, 21 CFR 864.8625

PRODUCT CODE:
MZG - Test component for Residual WBC in Leukoreduced Blood Components

PREDICATE DEVICE(S):
CEQer® Assay control
CD-Chex® Plus

DEVICE DESCRIPTION:
Each FluoroTrol™ Control Kit is a set of two controls containing a suspension of stabilized human-derived erythrocytes (RBC control) or platelets (PRP control) and residual leukocytes at a high and low concentration. Each FluoroTrol™ -rWBC/RBC Bi-Level Control Kit consists of one - 4.0 ml vial of Level-1 control, one - 4.0ml vial of Level-2 control, and one- 5 ml vial of Fluorescence Calibration Reagent. Each FluoroTrol™ – rWBC/PRP Bi-Level Control Kit consists of two - 5.0 ml vials of Level-1 control, two - 5.0 ml vials of Level-2 control, and one-5 ml vial of Fluorescence Calibration Reagent. Each reagent contains stabilized human erythrocytes or platelets, and residual leukocytes in a preservative medium.

INTENDED USE: FluoroTrol™ –rWBC/RBC Bi-Level Control Kit and the FluoroTrol™ -rWBC/PRP Bi-Level Control Kit are intended for use in test methods for enumerating residual leukocytes in red blood cell or platelet products. The external controls can be used for both manual counting methods and automated systems such as volumetric capillary cytometry.

EQUIVALENCE TESTING: An equivalency study comparing the FluoroTrol™ to the CEQer® Assay control or CD-Chex® Plus included evaluation of the variability of control results and an analysis of the distribution of out of range values between the control sera. The protocol gathered leukocyte enumeration data using the same technique under identical conditions.

Test results using the FluoroTrol™ –rWBC/PRP Bi-Level controls were comparable to the predicate CEQer® Assay Control, CD-Chex® PLUS control, in the Biometric Imaging CEQer® Assay. Differences between the 3 FluoroTrol™ production lots and 1 CD-Chex® lot were minor and not clinically significant. Coefficients of variation for FluoroTrol™ tended to be slightly lower than for CD-Chex® for both Level 1 and Level 2 concentrations and were all within clinically acceptable parameters. Furthermore, nearly all (66 of 69 or 96%) of the FluoroTrol™ Level 1 results were within an acceptable range, which was comparable to the CD-Chex® where 81 of 85 (95%) were within an acceptable range. All 70 of the FluoroTrol™ Level 2 results were within an acceptable range as were all 85 of the CD-Chex® results.

With regard to RBC, the FluoroTrol™ –rWBC/RBC Bi-Level controls were comparable to their CD-Chex® counterparts. No significant differences were observed with regard to variances or in the distribution of out of range values for either Level 1 or Level 2 concentrations.

In addition, the FluoroTrol™ has been verified through the Nageotte method to be substantially equivalent to the results obtained by the CEQer® Assay[1]. The CEQer® assay as referenced in the product insert was shown to be substantially equivalent to the Nageotte method. Testing has confirmed that the FluoroTrol™ performs appropriately under both assay methods.

[1] Dzik S, Moroff G, Dumont L, for the Biomedical Excellence for Safer Transfusion (BEST) Working Party of the ISBT, A multicenter study evaluating three methods for counting residual WBCs in WBC-reduced blood components: Nageotte hemocytometry, flow cytometry, and microfluorometry, *TRANSFUSION*, Vol 40, May 2000, pp 513-520.

CONCLUSION:

The FluoroTrol™ is substantially equivalent to the CEQer™ Assay control (i.e., to the CD-Chex® Plus (K960894) when used in the automated CEQer® Assay as instructed in the product package insert). Prior testing has demonstrated that the CEQer® Assay provides equivalent results to the Nageotte method. This, and the data obtained using the FluoroTrol™ with the Nagoette method, demonstrates that the FluoroTrol™ Control is also substantially equivalent to a Nageotte control method.