



BK000035

**510(k) Summary**  
***R&D Leuko-Reduced RBC Control***

Date of Summary: July 28, 2000  
Company Name: R&D Systems, Inc.  
614 McKinley Place N.E.  
Minneapolis, MN 55413  
Contact name: Kenneth T. Edds, Ph.D.  
612-379-2956, FAX 612-379-6580  
Classification name: hematology quality control mixture  
Product name: *R&D Leuko-Reduced RBC Control*  
CFR section: 864.8625  
Device Class: Class II

Device to which substantial equivalence is claimed:  
StatusFlow<sup>Pro</sup>, manufactured by R&D Systems, Inc.  
510(k) number: BK990005

The product is an assay control mixture for flow cytometric and manual determinations of residual WBCs present in RBC products. R&D Leuko-Reduced RBC Control™ is composed of human leukocytes and mammalian erythrocytes in a stabilizing medium.

Intended use: R&D Leuko-Reduced RBC Control is used to monitor methods for enumeration of residual leukocytes in leuko-reduced RBC products, including the dilution and staining process, method setup and WBC enumeration.

R&D Leuko-Reduced RBC Control has an intended use that is similar to the predicate device, i.e. it is a process control for WBC enumeration. The technology involved in using the two devices is similar although the mechanism of cell staining is different.

Nonclinical testing centered on the performance attributes of stability and precision. R&D Leuko-Reduced RBC Control passed the acceptance criteria of remaining within the assay range over the life of the product and conformed to precision limitations associated with such measurements. Expiration dating has been established at 60 days closed vial and 30 days or 20 thermal cycles open vial when stored at 2-8°C and handled according to instructions for use.