



BK000036

510(k) Summary
R&D Leuko-Reduced Plt 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 Plt Control*
CFR section: 864.8625
Device Class: Class II

Device to which substantial equivalence is claimed:
StatusFlow^{Pro}, 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 platelet products. R&D Leuko-Reduced Plt Control™ is composed of human leukocytes and mammalian platelets in a stabilizing medium.

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

R&D Leuko-Reduced Plt 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 Plt 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.

510(k) Number:

Device Name: *R&D Leuko-Reduced Plt Control*

Indications for Use:

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

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_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use _____

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)