

510(k) Summary
R&D Systems, Inc. Donor Checker Hematology Control

Date of Summary: December 16, 2003
Company Name: R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413
Contact name: Ralph E. Hogancamp
612-656-4413, FAX 612-379-6809

Classification name: Hematology Quality Control Mixture
Product name: R&D Donor Checker Hematology Control
CFR section: 864.8625 Hematology quality control mixture.
Device Class: Class II

Predicate Device: R&D Systems Glucose Hemoglobin Hematology Control, K993321 manufactured by R&D Systems, Inc. 614 McKinley Place N.E., Minneapolis, MN 55413

Description: This control is a hematology control mixture designed to monitor values obtained from HemoCue hematology instruments.

Intended use: R&D Donor Checker Hematology Control is designed to monitor values obtained from HemoCue Donor Hemoglobin Checker Analyzer.

Comparison: Both products are used to monitor hemoglobin on hematology instruments.

Discussion: Laboratory testing of 3 validation lots has shown R&D Donor Checker Hematology Control to have substantial equivalence in performance, precision and stability to the predicate device. R&D Donor Checker Hematology Control passed the acceptance criteria of remaining within the assay range over the life of the product. R&D Donor Checker Hematology Control has demonstrated precision as indicated by the small standard deviation obtained during laboratory testing. Expiration dating has been established at 45 days (closed vial) and 30 days (open vial) when stored at 2 - 8° C and handled according to instructions for use.

Conclusion: R&D Donor Checker Hematology Control is a safe and effective control for the above intended use when used as instructed in the package insert.