

510(k) Summary
R&D Systems, Inc. Plasma Hemoglobin Hematology Control

Date of Summary: July 27, 2004
Company Name: R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413
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612-656-4413, FAX 612-379-6809
Classification name: Hematology Quality Control Mixture
Product name: R&D Plasma Hemoglobin 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 Plasma/Low Hemoglobin Photometer.

Intended use: R&D Plasma Hemoglobin Hematology Control is designed to monitor values obtained from HemoCue Plasma/Low Hemoglobin Photometer.

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

Discussion: Laboratory testing of 3 validation lots has shown R&D Plasma Hemoglobin Hematology Control to have substantial equivalence in performance, precision and stability to the predicate device. R&D Plasma Hemoglobin Hematology Control passed the acceptance criteria of remaining within the assay range over the life of the product. R&D Plasma Hemoglobin Hematology Control has demonstrated precision as indicated by the small standard deviation obtained during laboratory testing. Expiration dating has been established at 180 days (closed vial) when stored at 2 - 8° C and 30 days (open vial) when stored at 2 - 8° C or controlled room temperature and handled according to instructions for use.

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