K961673

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510(k) SUMMARY
R&D Retic-PG™ HEMATOLOGY CONTROL

Date of Summary:	April 30, 1996
Company/Institution name:	R&D Systems, Inc. 614 McKinley Place N.E. Minneapolis, MN 55413-2647
Contact Person:	Sue Gallo Phone: (612) 379-2956 Fax: (612) 379-6580
Trade name:	R&D Retic-PG™
Classification/Common Name:	Hematology Quality Control Mixture (per 21 CFR 864.8625)
Classification Code/Device Class:	81JPK Hematology Control Mixtures for Quality Control/Class II

Substantial equivalence:
R&D Retic-PG Hematology Control is substantially equivalent to R&D Retic-I™, a hematology reticulocyte control currently being sold for in vitro diagnostic use. R&D Retic-I™ is a trademark of R&D Systems, Inc., 614 McKinley Place N. E., Minneapolis, MN 55413. The FDA document number for the predicate device, R&D Retic-I™, is K943336.

Device description:
R&D Retic-PG is an in vitro diagnostic reagent composed of human erythrocytes and a reticulocyte surrogate suspended in a plasma-like fluid with preservatives. It is composed of stable materials that provide a means of verifying accuracy and precision of CELL-DYN® 3500 reticulocyte results. CELL-DYN is a trademark of Abbott Diagnostics, Abbott Park, Illinois. R&D Retic-PG is available in three levels of reticulocytes and is stained and run in the same manner as patient specimens.

Intended use:
R&D Retic-PG™ is a tri-level, assayed hematology control designed to document and monitor reticulocyte values obtained from the CELL-DYN® 3500 System.

Comparison of R&D Retic-PG™ to the predicate device:
R&D Retic-PG™ has the same intended use as the predicate device. The products are used for different reticulocyte counting methods. The composition of R&D Retic-PG™ is the same as the predicate device except a reticulocyte surrogate is used instead of mammalian reticulocytes.

Discussion of performance data:
The determination of substantial equivalence is based on an assessment of performance data. Results of studies met acceptance criteria for stability tested by recovery of values within the Expected Range through the life of the product. The shelf life for this product is established as 62 days from shipment if stored at 2 - 8°C. The open-vial stability is 20 days.

Conclusions:
R&D Retic-PG™ is intended for use as a control to monitor the stability of reticulocyte values on the Abbott Cell-Dyn 3500 Hematology System. The stability data demonstrate that R&D Retic-PG™ is a stable material suitable for monitoring the performance of reticulocyte determinations on the Abbott Cell-Dyn 3500 System. R&D Retic-PG™ is substantially equivalent to R&D Retic-I currently sold for *in vitro* diagnostic use.

Submitted by:

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