



K970331

510(k) SUMMARY
CBC-4K™ HEMATOLOGY CONTROL

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Company/Institution name: R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413-2647

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Trade name: CBC-4K™ Hematology Control

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:

CBC-4K™ Hematology Control is substantially equivalent to CBC-3K™, a hematology control currently being sold for in vitro diagnostic use. CBC-3K™ is a trademark of R&D Systems, Inc., 614 McKinley Place N. E., Minneapolis, MN 55413. The FDA document number for the predicate device, CBC-3K™, is K904464.

Device description:

CBC-4K™ is an in vitro diagnostic reagent composed of human erythrocytes, mammalian leukocytes and platelets 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® Hematology Systems. Cell-Dyn® is a trademark of Abbott Diagnostics, Abbott Park, Illinois. CBC-4K™ is available in three levels of measured constituents and is run in the same manner as patient specimens.

Intended use:

CBC-4K™ is a tri-level hematology control designed to document and monitor values obtained from Cell-Dyn® hematology instruments.

Comparison of CBC-4K™ to the predicate device:

CBC-4K™ has the same intended use as the predicate device. The composition of CBC-4K™ is the same as the predicate device except a nucleated red blood cell surrogate has been added. This parameter is measured by the Cell-Dyn® 4000 but not by other models of Cell-Dyn® hematology analyzers.

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 80 days from shipment and the open-vial stability is 12 days provided that the product is properly handled according to the package insert instructions.

Conclusions:

CBC-4K™ is intended for use as a control to monitor the stability of values obtained from the Abbott Cell-Dyn® Hematology Systems. The stability data demonstrate that CBC-4K™ is a stable material suitable to use as a control. CBC-4K™ is substantially equivalent to CBC-3K™ currently sold for in vitro diagnostic use.

Submitted by:

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