2/17/99

K983032

510(k) SUMMARY
CBC-5D™ HEMATOLOGY CONTROL

Date of Summary:	August 27, 1998
Company/Institution name:	R&D Systems, Inc. 614 McKinley Place NE Minneapolis, MN 55413-2647
Contact Person:	Sue Gallo Phone: (612) 379-2956 Fax: (612) 379-6580
Trade name:	CBC-5D™ 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-5D™ Hematology Control is substantially equivalent to CBC-STK™, a hematology control previously cleared for in vitro diagnostic use. CBC-STK™ is a trademark of R&D Systems, Inc., 614 McKinley Place NE, Minneapolis, MN 55413. The FDA document number for the predicate device, CBC-STK™, is K934497.

Device description:
CBC-5D™ is an in vitro diagnostic reagent composed of human erythrocytes, simulated 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 Coulter® Hematology Systems. Coulter ® is a trademark of Coulter Electronics, Hialeah, FL. CBC-5D™ is available in three levels of measured constituents and is run in the same manner as patient specimens.

Intended use:
CBC-5D™ is a tri-level hematology control designed to document and monitor values obtained from Coulter® hematology instruments.

Comparison of CBC-4K™ to the predicate device:
CBC-5D™ has the same intended use as the predicate device. The composition of CBC-5D™ is the same as the predicate device except an avian red blood cell surrogate has been added.

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 52 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-5D™ is intended for use as a control to monitor the stability of values obtained from the Coulter® Hematology Systems. The stability data demonstrate that CBC-5D™ is a stable material suitable to use as a control. CBC-5D™ is substantially equivalent to CBC-STK™ previously cleared for *in vitro* diagnostic use.

Submitted by:
Sue Gallo

Sue Gallo, B.S., M.T. (ASCP)
Quality Assurance Coordinator

R&D Systems, Inc.
614 McKinley Place N.E. Phone: (612) 379-2956 WATS: (800) 428-4246 Customer Service
Minneapolis, MN 55413 FAX: (612) 379-6580 WATS: (800) 523-3395 Technical Service & QC Program

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 17 1999

Ms. Sue Gallo
Quality Assurance Coordinator
R & D Systems, Inc.
614 McKinley Place, N.E.
Minneapolis, Minnesota 55413

Re: K983032
Trade Name: CBC-5D™ Hematology Control/Multiple
Regulatory Class: II
Product Code: JPK
Dated: December 3, 1998
Received: December 4, 1998

Dear Ms. Gallo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

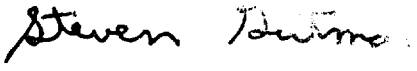
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Date: August 27, 1998

510(k) Number (if known): K983032

Device Name: **CBC-5D™**

Submitted by:
R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413

Indications for Use:

It is an established laboratory procedure to use stable controls to monitor the performance of diagnostic tests. CBC-5D™ is a tri-level hematology control designed to document and monitor values obtained from Coulter® hematology instruments.

Peter E. Maslen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983032

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)