K972172

JUL 24 1997

R&D SYSTEMS

510(k) SUMMARY
ESR Control-M™ HEMATOLOGY CONTROL

Date of Summary:	June 5, 1997
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:	ESR Control-M™ Hematology Erythrocyte Sedimentation Rate 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:
ESR Control-M™ Hematology Control is substantially equivalent to MSI HEMA-Trol™, a hematology control currently being sold for in vitro diagnostic use. MSI HEMA-Trol™ is a trademark of Medical Specialties International, Inc. 3610 Kennedy Road, South Plainfield, NJ 07080. The FDA document number for the predicate device, MSI HEMA-Trol™, is K940430.

Device description:
ESR Control-M™ is an in vitro diagnostic reagent composed of mammalian erythrocytes suspended in a plasma-like fluid with preservatives. It is composed of stable materials that provide a means of monitoring the performance of manual ESR procedures. Overall performance of the entire system is monitored including disposable ESR tubes, technique, and important environmental factors. ESR Control-M™ is available in two levels and is run in the same manner as patient specimens.

Intended use:
ESR Control-M™ is a bi-level hematology control designed to document and monitor values obtained from manual ESR procedures.

Comparison of ESR Control-M™ to the predicate device:
ESR Control-M™ has the same intended use as the predicate device. The composition of ESR Control-M™ is similar to the predicate device except mammalian erythrocytes are used instead of human erythrocytes thus eliminating the risks of exposure to human blood borne viruses.

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 45 days from shipment and the open-vial stability is 14 days provided that the product is properly handled according to the package insert instructions.

Conclusions:
ESR Control-M™ is intended for use as a control to monitor the performance of manual ESR procedures. The stability data demonstrate that ESR Control-M™ is a stable material suitable to use as a control. ESR Control-M™ is substantially equivalent to MSI HEMA-Trol™ currently sold 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
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kenneth Edds, Ph.D.
Manager, Regulatory Affairs
R & D Systems, Inc.
614 McKinley Place, N.E.
Minneapolis, Minnesota 55413

JUL 24 1997

Re: K972172
ESR Control-M™ Hematology Erythrocyte Sedimentation Rate Control
Regulatory Class: II
Product Code: JPK
Dated: June 5, 1997
Received: June 9, 1997

Dear Dr. Edds:

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

Steven Gutman

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: June 5, 1997

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510(k) Number (if known): _____

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

Device Name: **ESR Control-M™**

Indications for Use:

It is an established laboratory procedure to use stable controls to monitor the performance of diagnostic tests. ESR Control-M™ is a bi-level hematology control designed to document and monitor values obtained from manual ESR procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K97-178

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

(Optional Format 1-2-96)