



JUN 17 1999

K991876

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

Date of Summary: May 28, 1999
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: SEDRite™ Plus 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:

SEDRite™ Plus Hematology Erythrocyte Sedimentation Rate Control is equivalent to SEDRite™ Hematology Erythrocyte Sedimentation Rate Control currently being sold for *in vitro* diagnostic use. SEDRite™ is a trademark of R&D Systems, Inc. The FDA document number for the predicate device is K972172.

Device description:

SEDRite™ Plus 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 and automated ESR methods. Overall performance of the system is monitored including the analyzer, disposable equipment, and technique. SEDRite™ Plus is available in two levels and is run in the same manner as patient specimens.

Intended use:

SEDRite™ Plus is a bi-level control for use in monitoring erythrocyte sedimentation rate (ESR) values obtained from manual and automated ESR methods.

Comparison of SEDRite™ Plus to the predicate device:

SEDRite™ Plus has a similar intended use as the predicate device. The composition of SEDRite™ Plus is similar to the predicate device except for a proprietary change in the plasma-like fluid.

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. Stability was tested by recovery of values within the Expected Range through the life of the product. The shelf life for this product is established as 92 days from shipment and the open-vial stability is 36 days provided that the product is properly handled according to the package insert instructions.

Conclusions:

SEDRite™ Plus is intended for use as a control to monitor the performance of manual and automated ESR methods. The stability data demonstrate that SEDRite™ Plus is a stable material suitable to use as a control. SEDRite™ Plus is substantially equivalent to SEDRite™ control currently sold for *in vitro* diagnostic use.

Submitted by:

Sue Gallo, BS, MT (ASCP)
Quality Assurance Coordinator

May 28, 1998

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87(j))

Subject: Premarket Notification SEDRite™ Plus Hematology Erythrocyte
Sedimentation Rate Control

I certify that, in my capacity as Quality Assurance Coordinator of R&D Systems, Inc., I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Signature: Sue Gallo
Name: Sue Gallo

May 28, 1999
Dated



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN 17 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K991876
Trade Name: SEDRite™ Plus Hematology Erythrocyte Sedimentation Rate Control
Regulatory Class: II
Product Code: JPK
Dated: May 28, 1999
Received: June 2, 1999

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.

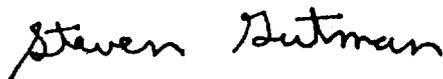
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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: May 28, 1999

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510(k) Number (if known): K991876

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

Device Name: SEDRite™ Plus

Indications for Use:

It is an established laboratory procedure to use stable controls to monitor the performance of diagnostic tests. SEDRite™ Plus is a bi-level control for use in monitoring erythrocyte sedimentation rate (ESR) values obtained from manual and automated ESR methods.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Steven E. Majumdar

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K991876

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)