

## 510(k) Summary

JAN 29 2010

### Submitter Information

R&D Systems, Inc.  
614 McKinley Place N.E.  
Minneapolis, MN 55413  
Contact: Nancy Ring  
Phone: 612-656-4533  
Fax: 612-379-6580  
Date Prepared: 1/7/2010

### Device Information

Proprietary Name:	XERet Hematology Control
Common Name:	Hematology Controls
Classification	21 CFR 864.8625
Classification Name:	Hematology Quality Control Mixture
Product Code:	JPK
Device Class:	II
Panel:	Hematology (81)

### Predicate Device

R&D Systems CBC-XE Hematology Control, (K042094) manufactured by R&D Systems, Inc. 614 McKinley Place N.E., Minneapolis, MN 55413.

### Description of Device

The R&D Systems XERet Hematology Control is an in vitro diagnostic reagent composed of human and porcine cells in a plasma-like fluid with preservatives. It is composed of stabilized materials that provide a means of monitoring reticulocyte counting methods. It is sampled in the same manner as a patient specimen.

### Intended Use:

XERet Control is a tri-level, assayed Hematology control designed to monitor values on Sysmex® hematology analyzers.

### Technological Comparison to Predicate

The new device has the same technological characteristics as the legally marketed predicate device. Both are used to perform quality control assays and both products are used to monitor values obtained from Sysmex® hematology analyzers. The predicate device is assayed for WBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, MPV, NEUT #, LYMPH #, MONO #, EO #, BASO #, NEUT%, MONO%, LYMPH%, EO%, BASO%, NRBC#, NRBC% , RBC, RET%, RET#, IRF, and RET-HE, whereas the R&D XERet Hematology Control is assayed for only RBC, RET%, RET#, and IRF parameters.

### **Summary of Performance Data**

Laboratory testing of 3 validation lots has shown the R&D XERet Hematology Control to have substantial equivalence in performance, precision and stability to the predicate device. The XERet Hematology Control passed the acceptance criteria of remaining within range over the life of the product. Expiration dating will be established at 85 days (closed vial) and 15 days (open vial) when stored at 2 - 8° C and handled according to instructions for use.

### **Substantial Equivalence Conclusion**

The data demonstrate that the R&D XERet Hematology Control is substantially equivalent to the legally marketed predicate device.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center-WO66-G609  
Silver Spring, MD 20993-0002

R & D Systems, Inc.  
c/o Ms. Nancy Ring  
Sr. QA/RA Specialist  
614 McKinley Place, N.E.  
Minneapolis, MN 55413

JAN 29 2010

Re: k100050

Trade/Device Name: R&D Systems CBC-XE Hematology Control  
Regulation Number: 21 CFR 864.8625  
Regulation Name: Hematology quality control mixture  
Regulatory Class: Class II  
Product Code: JPK  
Dated: January 7, 2010  
Received: January 8, 2010

Dear Ms. Ring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

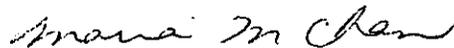
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requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.  
Director  
Division of Immunology and Hematology Devices  
Office of *In Vitro* Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K100050

Device Name: R&D XERet Hematology Control

### Indications for Use:

R&D XERet Control is a tri-level, assayed Hematology control designed to monitor values on Sysmex® hematology analyzers.

For *in vitro* Diagnostic Use Only

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K100050