

K091433

510(k) Summary

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: 10/05/09

OCT 28 2009

Device Information

Proprietary Name:	Retic-I Plus 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 Advia Retic Plus Hematology Control, (K010461) manufactured by R&D Systems, Inc. 614 McKinley Place N.E., Minneapolis, MN 55413.

Description of Device

The R&D Systems Retic-I Plus Hematology Control is an in vitro diagnostic reagent composed of human and avian erythrocytes in a plasma-like fluid with preservatives. It is composed of stabilized materials that provide a means of monitoring automated reticulocyte counting method. It is sampled in the same manner as a patient specimen.

Intended Use:

R&D Retic-I Plus Control is a tri-level, assayed hematology control designed to monitor values obtained from automated reticulocyte counting methods.

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 automated reticulocyte counting methods. The R&D Retic-I Plus Hematology Control is assayed for additional parameters.

Summary of Performance Data

Laboratory testing of 3 validation lots has shown the R&D Retic-I Plus Hematology Control to have substantial equivalence in performance, precision and stability to the predicate device. The Retic-I Plus Hematology Control passed the acceptance criteria of remaining within the assay range over the life of the product. Expiration dating will be established at 75 days (closed vial) and 14 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 Retic-I Plus Hematology Control is substantially equivalent to the legally marketed predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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. Quality Assurance/Regulatory Affairs Specialist
614 McKinley Place, N.E.
Minneapolis, MN 55413

OCT 28 2009

Re: k091433

Trade/Device Name: R&D Systems Retic-I Plus
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: JPK
Dated: September 16, 2009
Received: September 17, 2009

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 requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

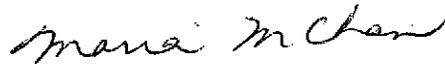
Page 2 – Ms. Ring

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): K091433

Device Name: R&D Retic-I Plus Hematology Control

Indications for Use:

R&D Retic-I Plus Control is a tri-level, assayed hematology control designed to monitor values obtained from automated reticulocyte counting methods.

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)

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

Page 1 of 1



Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) 091433