K072268

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

NOV 2 0 2007

Date Prepared: 8/14/07

Device Information

Proprietary Name:	HC WBC 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-3K Hematology Control, (K904464) manufactured by R&D Systems, Inc. 614 McKinley Place N.E., Minneapolis, MN 55413.

Description of Device

The HC WBC Hematology Control is an in vitro diagnostic control composed of human erythrocytes and bovine leukocytes in a plasma-like fluid with preservatives. It is an assayed whole blood control designed to monitor values obtained from analyzers that measure white blood cell counts in whole blood. It is sampled in the same manner as a patient specimen.

Intended Use:

HC WBC Control is an assayed whole blood control designed to monitor values obtained from analyzers that measure white blood cell counts in whole blood. Refer to the assay table for specific instrument models.

Technological Comparison to Predicate

The new device has the same technological characteristics as the legally marketed predicate device. Both products are used to monitor values from analyzers that measure white blood cell counts in whole blood. Both are used to perform quality controls assays. The HC WBC Hematology Control has monitors a single parameter.

Summary of Performance Data

Laboratory testing of 3 validation lots has shown the HC WBC Hematology Control to have substantial equivalence in performance, precision and stability to the predicate device. The HC WBC Hematology Control passed the acceptance criteria of remaining within the assay range over the stated life of the product. The HC WBC Hematology Control has demonstrated precision as indicated by the standard deviation and % CV's obtained during laboratory testing.

Substantial Equivalence Conclusion

The data demonstrates that the HC WBC Hematology Control is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 0 2007

R & D Systems, Inc.
C/O Nancy C. Ring
614 McKinley Place, NE
Minneapolis, Minnesota 55413

Re: k072268
Trade/Device Name: HC WBC Hematology Control, Model: WBC00S
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: Class II
Product Code: JPK
Dated: August 14, 2007
Received: August 15, 2007

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 either class II (Special Controls) or class III (PMA), 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); and good manufacturing practice 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 Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K072268

Device Name: HC WBC Hematology Control

Indications for Use:

It is an established laboratory procedure to use stable controls to monitor the performance of diagnostic tests. The HC WBC Hematology Control is designed to monitor values obtained from analyzers that measure white blood cell counts in whole blood.

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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K072268