K072096

AUG 2 0 2007

510(k) Summary

Submitter Information

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

Contact: Nancy Ring
Phone: 612-656-4533
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Date Prepared: 7/30/07

Device Information

Proprietary Name:	CBC-5D Plus Retics 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-5D Hematology Control, (K983032) manufactured by R&D Systems, Inc. 614 McKinley Place N.E., Minneapolis, MN 55413.

Description of Device

CBC-5D Plus Retics is an in vitro diagnostic control composed of human erythrocytes, simulated leukocytes, and mammalian platelets in a plasma-like fluid with preservatives. It is composed of stable materials that provide a means of monitoring the performance of Coulter® hematology analyzers. It is sampled in the same manner as a patient specimen.

Intended Use:

The CBC-5D Plus Retics is a control designed to monitor values on Coulter® hematology analyzers. Refer to assay sheet 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 Coulter® hematology instruments. Both are used to perform quality controls assays. The CBC-5D Plus Retics Hematology Control has an additional parameter.

Summary of Performance Data

Laboratory testing of 3 validation lots has shown the CBC-5D Plus Retics Hematology Control to have substantial equivalence in performance, precision and stability to the predicate device. The CBC-5D Plus Retics Hematology Control passed the acceptance criteria of remaining within the assay range over the life of the product. The CBC-5D Plus Retics Hematology Control has demonstrated precision as indicated by the small standard deviation and % CV's obtained during laboratory testing. Expiration dating will be established at 105 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 demonstrates that the CBC-5D Plus Retics 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

AUG 20 2007

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

Re: k072096
Trade/Device Name: CBC-5D Plus Retics Hematology Control
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: Class II
Product Code: JPK
Dated: July 30, 2007
Received: July 31, 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0484. 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,

Robert L. Becker, Jr., MD, PhD
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): K072096

Device Name: CBC-5D Plus Retics Hematology Control

Indications for Use:

It is an established laboratory procedure to use stable controls to monitor the performance of diagnostic tests. The CBC-5D Plus Retics Hematology Control is designed to document and monitor values obtained from Coulter® hematology instruments.

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

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