DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 1, 2016

R&D Systems, Inc.
Rachel Somsen
Associate Director, Quality Assurance and Regulatory Affairs
614 McKinley Place N.E.
Minneapolis, MN 55413

Re: K160606
Trade/Device Name: BC-5D Hematology Controls
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: Class II
Product Code: JPK
Dated: August 3, 2016
Received: August 5, 2016

Dear Ms. Somsen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Kelly Oliner -S

For
Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160606

Device Name
BC-5D Hematology Controls

Indications for Use *(Describe)*
BC-5D is an assayed whole blood control designed for Mindray BC-5390 (Mindray 5000 series) Auto Hematology Analyzer for the following parameters: WBC, Neu#, Lym#, Mon#, Eos#, Bas#, Neu%, Lym%, Mon%, Eos%, Bas%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, and MPV.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter Information

R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413
Contact: Rachel Somsen
Phone: 612-851-4846
Fax: 612-379-6580
Date Prepared: August 26, 2016

Device Information

Proprietary Name:	BC-5D Hematology Controls
Common Name:	Hematology Control
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)

Instrument

Mindray BC-5390 Hematology Analyzer (K160429)

Description of Device

The Mindray BC-5390 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for In Vitro Diagnostic Use in clinical laboratories. It is only to be used by trained medical professionals to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.

The BC-5D Hematology Control consists of three levels of controls (Low, Normal, and High). It is recommended to perform quality control check using these controls established by the laboratory procedures and/or local/national regulations.

BC-5D Hematology Control is an *in vitro* diagnostic reagent composed of human erythrocytes, simulated leukocytes, and mammalian platelets in a plasma-like fluid with preservatives. This control is contains stabilized materials that provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

Intended Use

BC-5D is an assayed whole blood control designed for Mindray BC-5390 (Mindray 5000 series) Auto Hematology Analyzer for the following parameters: WBC, Neu#, Lym#, Mon#, Eos#, Bas#, Neu%, Lym%, Mon%, Eos%, Bas%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, and MPV.

Technological Comparison to Predicate

The subject device has the same technological characteristics as the legally marketed predicate device. The BC-5D Hematology Control is intended to be used to monitor values obtained on Mindray BC-5000 series hematology analyzers. The predicate device is used to monitor values obtained on Sysmex Hematology Instruments.

The predicate device is assayed for : WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, PDW, MPV, P-LCR, IRF, NEUT#, LYMPH#, MONO#, EO#, BASO#, NRBC#, RET#, Neut%, Lymph%, Mono%, Eo%, Baso%, Nrbc%, and Ret%.

Summary of Performance Data

Following the manufacture and analysis of three verification lots from which the “assay range” for each parameter was determined, 3 validation lots of BC-5D Hematology Controls were manufactured and tested. Results verified the product to have substantial equivalence in performance, precision and stability to the predicate device. The BC-5D Hematology Control met the acceptance criteria, as determined during verification, over the life of the product. Expiration dating is 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 demonstrates that the BC-5D Hematology Control is substantially equivalent to the legally marketed predicate device.