APR 2 8 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K101578 .

Submitter Information

Manufacturer:	R&D Systems, Inc.
Address:	614 McKinley Place N.E. Minneapolis, MN 55413
Contact:	Nancy Ring
Phone:	612-656-4533
Fax:	612-379-6580
Date Prepared:	4/21/2011

Device Information

Trade Name:	Body Fluid-I Hematology Control
Common Name:	Hematology Control
Classification Name:	Hematology quality control mixture
Classification:	21 CFR 864.8625
Product Code:	JPK
Device Class:	II
Panel:	Hematology (81)

Predicate Device

Trade Name:	Streck Cell-Chex™ Auto Hematology Control
510(k) number:	K053362
Date:	January 13th, 2006

Description of Device

The R&D Body Fluid-I is an assayed, in vitro, whole blood control composed of human and bovine cells in a plasma-like fluid with preservatives. Three levels are available and each level of control is packaged in a tube containing 3 mL of the control material. It is sampled in the same manner as a patient specimen.

Intended Use:

Body Fluid-I Control is an assayed hematology control intended to monitor the reliability of hematology instruments that quantitatively measure red and white blood cell counts in cerebrospinal fluids, serous fluids, and synovial fluids.

Comparison to Predicate

Like the previously cleared predicate device, the Body Fluid-I Hematology Control is an assayed whole blood control for evaluating the accuracy and precision of hematology instruments that measure blood cell counts in patient body fluid samples.

The difference is the predicate device's biological source is human whereas the Body Fluid-I contains human and bovine biological sources.

Summary of Data

Three lots were tested to verify the closed vial and open vial stability and lot to lot reproducibility. Each lot of control material (each lot containing 3 levels) were stored at 2 - 8° C and tested at real time points at approximately every other week on three different instruments for the purpose of evaluating closed vial stability.

Open vial stability was assessed on three lots of control material (each lot containing 3 levels) and tested near the end of their closed vial shelf life to reflect a worse case scenario. The controls were stored at 2 - 8° C until they were tested. The testing was done according to the instructions for use through at least 30 days and run on one analyzer.

The Body Fluid-I Hematology Control passed the acceptance criteria of remaining within range over the life of the product.

Conclusions Drawn From Tests:

The R&D Systems Body Fluid-I Hematology Control is as safe and effective as the predicate device and is an effective quality control material for evaluating the accuracy and precision of hematology instruments that measure blood cell counts in patient body fluid samples when used as indicated on the labeling. It meets the claim of a 75 day closed vial, and 30 day open vial stability and results confirm lot-to-lot consistency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

APR 2 8 2011

R&D Systems, Inc.
c/o Ms. Nancy Ring
Sr. Quality Assurance/Regulatory Affairs Specialist
614 McKinley Place N.E.
Minneapolis, MN, 55413

Re: k101578
Trade/Device Name: Body Fluid-I Hematology Control
Regulation Number: 21 CFR 864.8625
Regulation Name: Mixture, Hematology Quality Control
Regulatory Class: Class II
Product Code: JPK
Dated: April 8, 2011
Received: April 12, 2011

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

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

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): K101578

Device Name: R&D Body Fluid-I Hematology Control

Indications for Use:

The R&D Body Fluid-I Control is an assayed hematology control intended to monitor the reliability of hematology instruments that quantitatively measure red and white blood cell counts in cerebrospinal fluids, serous fluids, and synovial fluids.

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) K101578