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510(k) Summary
R&D Systems, Inc. Sickle QC Hematology Control

Date of Summary:	February 2, 2007
Company Name:	R&D Systems, Inc. 614 McKinley Place N.E. Minneapolis, MN 55413
Contact name:	Ralph E. Hogancamp 612-656-4413, FAX 612-379-6809
Classification name:	Sickle Cell Test
Product name:	R&D Sickle QC Hematology Control
CFR section:	21 CFR 864.7825 Sickle Cell Test
Device Class:	Class II

Predicate Device: Streck Sickle-Chex, K013316, November 06, 2001, Streck Laboratories, Inc., 7002 South 109th Street, LaVista, NE 68128.

Description: Sickle QC is a control for solubility tests used to detect Hemoglobin S. Sickle QC is compatible with other manufacturer's solubility kits.

The control contains human red blood cells that are processed and are suspended in an anti-microbial solution that completes the simulation of fresh whole blood.

Intended use: R&D Sickle QC Hematology Control is intended to be used as a sickle cell control in testing for the presence of Hemoglobin S in solubility tests.

Comparison: Both products are used as sickle cell controls in testing for Hemoglobin S in solubility tests. .

Discussion: Laboratory testing of 3 validation lots has shown R&D Sickle QC Hematology Control to have substantial equivalence in performance, precision and stability to the predicate device. R&D Sickle QC Hematology Control passed the acceptance criteria of remaining within the assay range over the life of the product. R&D Sickle QC Hematology Control has demonstrated precision as indicated by the small standard deviation obtained during laboratory testing. Expiration dating has been established at 6 months (closed vial) and 100 days (open vial) when stored at 2 - 8° C and handled according to instructions for use.

Conclusion: R&D Sickle QC Hematology Control is a safe and effective control for the above intended use when used as instructed in the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

R & D SYSTEMS, INC.
614 McKinley Pl., N.E.
Minneapolis, MN 55413
Attn: Ralph E. Hogancamp

MAR 2 9 2007

Re: k070334
Trade/Device Name:
Regulation Number: 21 CFR 864.7825
Regulation Name: Hematology Quality Control Material
Regulatory Class: Class II
Product Code: GGM
Dated: February 02, 2007
Received: February 26, 2007

Dear Mr. Hogancamp:
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 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 Part 801); 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.
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 Compliance at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

K070334

Device Name: R&D Sickle QC Hematology Control

Indications for Use:

R&D Sickle QC Hematology Control is intended to be used as a sickle cell control in testing for the presence of Hemoglobin S in solubility tests.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X_ OR Over-The-CounterUse_____

(Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K070334