NOV 1 2 1999

510(k) Summary

R&D Glucose/Hemoglobin ™ Whole Blood Control

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 K993321.

Date of Summary:	September 30, 1999
Company Name:	R&D Systems, Inc. 614 McKinley Place N.E. Minneapolis, MN 55413
Contact name:	Kenneth T. Edds, Ph.D. 612-379-2956, FAX 612-379-6580
Classification name:	~~tcr~~
Product name:	*R&D Glucose/Hemoglobin ™ Whole Blood Control*
CFR section:	
Device Class:	Class II

Device to which substantial equivalence is claimed:
HQ-Chex, manufactured by Streck Laboratories, Omaha, NE.
510(k) number: K961195

Intended use: *R&D Glucose/Hemoglobin ™ Whole Blood Control* is an assayed whole blood product for monitoring the accuracy and precision of analyzers that measure glucose and hemoglobin in whole blood.

The product is composed of human erythrocytes and glucose in a plasma-like fluid with preservatives.

R&D Glucose/Hemoglobin ™ Whole Blood Control has an intended use that is similar to the predicate device. The technology of the two devices is similar.

Nonclinical testing centered on the performance attributes of stability and precision. *R&D Glucose/Hemoglobin ™ Whole Blood Control* passed the acceptance criteria of remaining within the assay range over the life of the product. Expiration dating has been established at 205 days closed vial and 30 open vial when stored at 2-8°C and handled according to instructions for use. Vials kept at ambient temperature have an open vial stability of 7 days.

R & D Systems, Inc.
614 McKinley Place N.E. PHONE: (612) 379-2956 WATS: (800) 343-7475
Minneapolis, MN 55413 FAX: (612) 379-6580 E-MAIL: info@rndsystems.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 2 1999

Kenneth T. Edds, Ph.D.
Regulatory Affairs Manager
R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, Minnesota 55413

Re: K993321
Trade Name: R & D Glucose/Hemoglobin™ Whole Blood Control
Regulatory Class: II Product Code: GGM
I JJY
Dated: October 1, 1999
Received: October 4, 1999

Dear Dr. Edds:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K993321

Device Name:R&D Glu/Hgb Control)

Indications for Use: R&D Glu/Hgb Control is an assayed whole blood product used to monitor the precision and accuracy of analyzers that measure glucose and hemoglobin in whole blood.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices K993321
510(k) Number

Prescription Use ✓ OR Over-The-CounterUse

(Optional Format 1-2-96)