



NOV 12 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: ~~ter~~  
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.

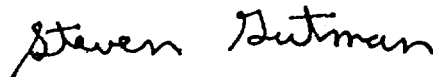


Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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

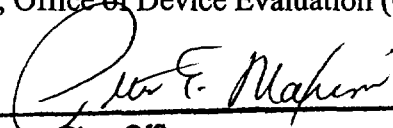
510(k) Number: K993321

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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number \_\_\_\_\_

K993321

Prescription Use

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)