JAN 2 2 2002

K013898

510(k) Summary
R&D Systems, Inc. RET-LINE

Date of Summary:	December 13, 2001
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:	Hematology quality control mixture
Product name:	R&D RET-LINE
CFR section:	864.8625 Hematology quality control mixture.
Device Class:	Class II

Predicate Device: Retic Chex Linearity, manufactured by Streck Laboratories, 14306 Industrial Rd. Omaha, NE 68144.
510(k) number: K000115

Description: R&D RET-LINE is a multi-level suspension of human erythrocytes and mammalian erythrocytes suspended in a simulated plasma fluid with preservatives packaged in a glass vial with a silicon rubber closure containing 3.0 mL of reagent.

Intended use: R&D RET-LINE Kit is a multi-level linearity control that provides a means of measuring the linearity of automated hematology analyzers for reticulocyte parameter determinations.

Comparison with Predicate Device: R&D RET-LINE and Retic Chex Linearity are multi-level devices intended for verification of reticulocyte analysis on a variety of automated hematology instruments. Both contain stabilized human red blood cells and simulated human reticulocytes that properly mimic human whole blood on the intended use analyzers. Both cover a range of reticulocyte percentages that model reportable patient ranges and both comprise a true linearity and can be used to verify the linear operation of the intended hematology analyzers.

Discussion: Nonclinical testing of three validation lots focused on the performance attributes of stability and linearity assessment. R&D RET-LIN passed the acceptance criteria of remaining within the assay ranges over the life of the product. R&D RET-LINE also met linearity specifications. Expiration dating has been established at 75 days (closed vial) when stored at 2 – 8 °C and handled according to instructions for use. Normal use of this product is to use it once and discard any leftover product, therefore, is no open vial stability claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 2 2002

Mr. Ralph E. Hogancamp
Quality Specialist
R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, Minnesota 55413

Re: K013898
Trade/Device Name: R&D RET-LINE Kit
Regulation Number: 21 CFR § 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: II
Product Code: JPK
Dated: January 10, 2002
Received: January 11, 2002

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 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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

Device Name: R&D RET-LINE Kit

Indications for Use:

R&D RET-LINE Kit is a multi-level linearity control that provides a means of measuring the linearity of automated hematology analyzers for reticulocyte parameter determinations.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013898

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____

(Optional Format 1-2-96)