510(k) Summary of Safety and Effectiveness

K070199

510(k) Submitter:

Streck
7002 South 109th Street
Omaha, NE 68128

Official Correspondent:

Carol Thompson
Quality Assurance Manager
(402) 537-5313

FEB 23 2007

Date Prepared: January 19, 2007

Names of Device:

Trade Name: Retic-Chex® Linearity for BC
Common Name: Hematology Linearity Material
Classification Name: Hematology quality control mixture (§ 864.8625)

Predicate Devices: Retic-Chex Linearity manufactured by Streck

Description:

Retic-Chex Linearity for BC is a suspension of stabilized human red blood cells and simulated human reticulocytes packaged in plastic vials, containing 3.0 mL volumes. The device consists of five levels of reticulocyte percentage range from 0 to 29.5%. Closures are injection molded polypropylene screw top caps. The vials are packaged in a welled vacuum formed clam-shell container with the package insert and assay sheet.

Intended Use:

Retic-Chex Linearity for BC is an assayed linearity control kit, which can be used to assess the instrument's accuracy and to verify patient reportable ranges of automated hematology instrumentation capable of enumerating reticulocytes.

Comparison with Predicate Devices:

	Predicate – Retic-Chex Linearity	Product – Retic-Chex Linearity for BC
Closed Vial Stability	105 days	105 days
Open Vial Stability	5 days	5 days
Intended Use	Retic-Chex Linearity is a multi level calibration (linearity) assessment kit for reticulocyte counting. It is designed for use on the following instruments: Bayer Advia 120, Sysmex R-3000, Sysmex XE-2100, and Abbott Cell-Dyn 4000. Use of this kit allows users to satisfy CAP requirements and CLIA recommendations to verify patient reportable ranges.	Retic-Chex Linearity for BC is an assayed linearity control kit, which can be used to assess the instrument's accuracy and to verify patient reportable ranges of automated and semi-automated hematology instrumentation capable of enumerating reticulocytes.
Formulation		Same formula as Retic-Chex Linearity. The only difference is the way the retics are processed.
Storage Conditions	2 - 10°C	2 - 10°C
Level 1 range	0.4% - 1.1%	0.4% - 1.1%
Level 2 range	4.4% - 5.6%	4.7% - 6.8%
Level 3 range	8.6% - 10.0%	9.5% - 12.0%
Level 4 range	12.7% - 14.4%	14.2% - 17.2%
Level 5 range	23% - 25%	26.5% - 29.5%

Discussion of Tests and Test Results:

Three studies of Retic-Chex Linearity for BC were conducted:
I) Run to Run Reproducibility and Comparison to Whole Blood; II) Long Term Stability; and III) Open Vial Stability. Study results showed Retic-Chex Linearity for BC to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating.

Conclusions Drawn From Tests:

Study results show Retic-Chex Linearity for BC to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating. Retic-Chex Linearity for BC is a safe and effective product, which fulfills its intended use when used as instructed in the product package insert.

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

STRECK
C/O Kerrie Oetter
7002 South 109th Street
Omaha, Nebraska 68128

FEB 23 2007

Re: k070199
Trade/Device Name: Retic-Chex Linearity for BX
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: Class II
Product Code: JPK
Dated: January 19, 2007
Received: January 22, 2007

Dear Ms. Oetter:
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

510(k) Number (if known): K070199

Device Name: Retic-Chex® Linearity for BC

Indications For Use:

Retic-Chex Linearity for BC is an assayed linearity kit, which can be used to assess the instrument's accuracy and to verify patient reportable ranges of automated hematology instrumentation capable of enumerating reticulocytes.

Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) K070199