K994388

JAN 14 2000

510(k) Summary of Safety and Effectiveness

510(k) Submitter:

Streck Laboratories, Inc.
14124 Industrial Road
Omaha, NE 68144

Official Correspondent:

Paul Kittelson
Quality Assurance
(402) 691-7465

Date Prepared:

December 27, 1999

Names of Device:

Trade Name:	XE Check
Common Name:	Assayed hematology control
Classification Name:	Hematology quality control mixture (§ 864.8625)

Predicate Devices:

SF Check manufactured by Streck Laboratories, Inc.
Retic Chex manufactured by Streck Laboratories, Inc.

Description: XE Check is a suspension of stabilized human red blood cells, human white cells, simulated human platelets, and simulated human reticulocytes packaged in glass vials containing 4.6 mL volumes. Closures are injection molded polypropylene screw-top caps. The vials are packaged in polystyrene jars.

Intended Use: XE Check is intended to be used as a control for evaluating complete blood cell count (CBC), white cell five-part differential, and reticulocyte percentage on Sysmex XE – 2100 series hematology instruments. The device will consist of three levels: Abnormal Low (characterized by low CBC, high reticulocyte %), Normal (normal CBC, normal reticulocyte %), and Abnormal High (high CBC, low reticulocyte %).

Comparison with Predicate Devices: Like SF Check, XE Check is intended to enable the user to verify satisfactory performance of Sysmex XE – 2100 instruments in recovery of CBC and white cell differential parameters on whole blood specimens. Both devices contain stabilized human red blood cells, human white cells, and simulated platelets which properly mimic human whole blood components on Sysmex XE – 2100.

Unlike SF Check, XE Check contains a stabilized human reticulocyte component, similar to Retic Chex. This allows the user to verify proper performance of the on-line reticulocyte analysis system in Sysmex XE – 2100 instruments with the same device used for CBC and white cell differential analysis verification.

Discussion of Tests and Test Results: Three studies of XE Check were conducted: I) Lot to Lot Reproducibility and Comparison to Whole Blood; II) Long Term Stability; and III) Open Vial Stability. Study results showed XE Check to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating.

Conclusions Drawn From Tests: XE Check is safe and effective for controlling CBC/Diff/Retic parameters on Sysmex XE – 2100 instruments when used as instructed in the product package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 14 2000

Mr. Paul Kittelson
Quality Assurance
Streck Laboratories, Inc.
14124 Industrial Road
Omaha, Nebraska 68144

Re: K994388
Trade Name: XE Check
Regulatory Class: II
Product Code: GLQ, JPK
Dated: December 27, 1999
Received: December 28, 1999

Dear Mr. Kittelson:

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 (if known): K994388

Device Name: XE Check

Indications For Use:

XE-Check is intended to be used as a control for complete blood cell count (CBC), white cell 5-part differential, and reticulocyte parameters on Sysmex XE – 2100 hematology instrument.

(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
510(k) Number K994388

Prescription Use ✓ OR **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)