K992887

NOV 22 1999

510(k) Summary of Safety and Effectiveness

510(k) Submitter:

Streck Laboratories, Inc.
P.O. Box 45625
Omaha, NE 68145-0625

Official Correspondent:

Paul Kittelson
Quality Assurance/Regulatory Affairs
(402) 691-7465

Date Prepared:

August 25, 1999

Names of Device:

Trade Name:	STaK-Chex Plus Retics
Common Name:	Assayed hematology control
Classification Name:	White and red cell (and reticulocyte) control (§ 864.8625)

Predicate Device:

STaK-Chex (K911582) manufactured by Streck Laboratories
Retic-Chex (K905524) manufactured by Streck Laboratories

Description: STaK-Chex Plus Retics is a suspension of stabilized human red blood cells, human white cells, simulated human platelets, and simulated human reticulocytes packaged in glass vials containing 4.5 mL volumes. Closures are injection molded polypropylene screw-top caps. The vials are packaged in polystyrene jars.

Intended Use: STaK-Chex Plus Retics is intended to be used as a control for complete blood cell count (CBC), white cell five-part differential, and reticulocyte parameters on Beckman/Coulter GenS series hematology instruments.

Comparison with Predicate Device: Like STaK-Chex, STaK-Chex Plus Retics is intended for CBC/WBC differential performance validation of Beckman/Coulter GenS hematology instruments. Both devices contain stabilized human red blood cells, human white cells, and simulated platelets which properly mimic human whole blood components on Beckman/Coulter STK-S and GenS analyzers.

Unlike STaK-Chex, STaK-Chex Plus Retics contains a stabilized human reticulocyte component. This allows the GenS user to control CBC, WBC differential, and on-line reticulocyte analysis simultaneously with a single device.

Discussion of Tests and Test Results: Four studies of STaK-Chex Plus Retics were conducted: I) Run to Run Reproducibility and Comparison to Whole Blood; II) Site to Site Reproducibility; III) Long Term Stability; and IV) Open Vial Stability. Study results showed STaK-Chex Plus Retics to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating.

Conclusions Drawn From Tests: STaK-Chex Plus Retics is safe and effective for controlling CBC, WBC differential and reticulocyte parameters on Beckman/Coulter GenS instruments when used as instructed in the product package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 22 1999

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

Re: K992887
Trade Name: StaK-Chex® Plus Retics
Regulatory Class: II
Product Code: GLQ
Dated: August 25, 1999
Received: August 27, 1999

Dear Mr. Kettelson:

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K992887

Device Name: STaK-Chex® Plus Retics

Indications For Use:

StaK-Chex Plus Retics is intended to be used as a control for complete blood cell count (CBC), white cell 5-part differential, and reticulocyte parameters on Beckman/Coulter GenS series hematology instruments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maskow

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992887

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

(Optional Format 1-2-96)