K090137

510(k) Summary of Safety and Effectiveness

MAR 1 8 2009

510(k) Submitter: Streck
7002 South 109th Street
Omaha, NE 68128

Official Correspondent: Carol Thompson, Quality Assurance Manager
(402)-537-5213

Date Prepared: January 19, 2009

Name of Device:
Trade Name: STaK-Chex® Plus Retics
Common Name: Assayed Hematology Control
Classification Name: Hematology quality control mixture (864.8625)

Predicate Device: STaK-Chex Plus Retics (K992887) Manufactured by Streck

Description:
STaK-Chex Plus Retics is a stabilized suspension of human red blood cells, a nucleated red blood cell analog, a white blood cell component consisting of human and non-human analogs and a platelet component consisting of a non-human analog in a preservative medium. The product is packaged in plastic vials containing 5ml. The closures are polypropylene screw caps with polyethylene liners. There are three different levels (low, normal and high). The vials will be packaged in a six (6) or twelve (12) welled vacuum formed "clam-shell" container with the package insert / assay sheet. The product must be stored at 2 - 10° C.

Intended Use:
STaK-Chex Plus Retics is an assayed whole blood control for evaluating the accuracy and precision of automated, semi-automated and manual procedures that measure blood cell parameters.

Comparison to Predicate Device:

	STaK-Chex Plus Retics (Predicate Product)	STaK-Chex Plus Retics
Intended Use Statement	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.	STaK-Chex Plus Retics is an assayed whole blood control for evaluating the accuracy and precision of automated, semi-automated and manual procedures that measure blood cell parameters.
Open Vial Stability	14 days	Same
Closed Vial Stability	105 days	75 days
Reagents	Stabilized human and animal blood	Low Level - Stabilized human and animal blood, plus a nucleated red blood cell analog Normal and High Levels same as Predicate
Storage Conditions	2 - 10°C	Same

Discussion of Tests and Test Results:
Four types of studies were conducted to establish performance of STaK-Chex Plus Retics. The four tests conducted were Closed Vial Stability, Open Vial Stability, Run to Run Reproducibility, and External Site recovery of values. All testing showed that STaK-Chex Plus Retics is consistently reproducible, substantially equivalent to the predicate product and stable for the shelf life claimed.

Conclusions Drawn From Tests:
Study results show STak-Chex Plus Retics to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating. STaK-Chex Plus Retics is a safe and effective product, which fulfills its intended use 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

MAR 18 2009

Streck, Inc.
c/o Ms. Kerrie Oetter
Quality Assurance Coordinator
7002 South 109th St.
Omaha, Nebraska 68128

Re: k090137
Trade/Device Name: STaK-Chex ® Plus Retics.
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control mixture
Regulatory Class: II
Product Code: GLQ
Dated: March 4, 2009
Received: March 10, 2009

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 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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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 the labeling regulation, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240- 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For question regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR), please contact the Division of Surveillance Systems at 240-276-3464. You many obtain other general information on your responsibilities under the Act from the Division of Small Manufactuers, 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,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: **STaK-Chex Plus Retics**

Indication For Use:

STaK-Chex Plus Retics is an assayed whole blood control for evaluating the accuracy and precision of automated procedures that measure blood cell parameters.

Prescription Use __X___ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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