K083200

510(k) Summary of Safety and Effectiveness

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

Date Prepared: October 22, 2008

FEB - 3 2009

Names of Device:
Trade Name: X-Cal™
Common Name: Assayed hematology calibrator
Classification Names: Calibrator for Cell Indices (864.8150)
Classification Numbers: KRX

Predicate Devices: Cal-Chex– K840261

Description: X-Cal is a stabilized suspension of human and animal blood, in a solution containing biological salts and anti-microbial preservatives. The product is packaged in plastic vials containing 4.5 ml. The closures are polypropylene screw caps with polyethylene liners. The vials will be packaged in a five welled vacuum formed "clam-shell" container. The product must be stored at 2 - 8°C.

Intended Use: X-Cal is used to calibrate and verify calibration of Sysmex hematology analyzers. Refer to product assay sheet.

Comparison with Predicate Devices:

	Cal-Chex (Predicate Product)	X-Cal
Intended Use Statement	Cal-Chex is used to calibrate multi-parameter hematology analyzers	X-Cal is used to calibrate Sysmex hematology analyzers.
Open Vial Stability	5 days	24 hours
Closed Vial Stability	45 days	34 days
Reagents	Stabilized Human and Animal Blood	Same
Storage Conditions	2 - 10°C	2 - 8°C

Discussion of Tests: Three studies of X-Cal were conducted: Run to Run Reproducibility and Comparison to Whole Blood; Open Vial Stability and Closed Vial Stability.

Conclusions Drawn From Tests: Study results show X-Cal to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating. X-Cal 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

Streck Inc.
c/o Ms. Erin Johnson
Quality Assurance Coordinator
7002 South 109th St.
Omaha, NE 68128

FEB - 3 2009

Re: k083200
Trade/Device Name: X-Cal™
Regulation Number: 21 CFR 864.8150
Regulation Name: Calibrator for Cell Indices
Regulatory Class: Class II
Product Code: KRX
Dated: January 09, 2009
Received: January 12, 2009

Dear Ms. Johnson:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions 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 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,

Maria M. Chan, Ph.D.
Acting Division 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): K083200

Device Name: X-Cal™

Indication For Use:

X-Cal is used to calibrate and verify calibration of Sysmex hematology analyzers. Refer to product assay sheet.

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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