

K083926

### 510(k) Summary of Safety and Effectiveness

**510(k) Submitter:** Streck  
7002 South 109<sup>th</sup> Street  
Omaha, NE 68128

FEB 11 2009

**Official Correspondent:** Carol Thompson, Quality Assurance Manager  
(402) 537-5313

**Date Prepared:** December 30, 2008

**Names of Device:**

Trade Name: **CD4 Count**  
Common Name: Immunophenotyping Control  
Classification Name: White Cell Control, 21CFR864.8625

**Predicate Device:** CD-Chex<sup>®</sup> Plus BC (K051633)

**Description:**

CD4 Count is a suspension of stabilized human blood packaged in a plastic vial containing 2.5 mL volumes. The vials are packaged in a vacuum formed "clam-shell" box.

**Intended Use:**

CD4 Count is intended to be used as an assayed whole blood quality control for evaluating white blood cell subsets on a flow cytometry instrument

**Comparison with Predicate Device:**

	<b>CD-Chex Plus BC (Predicate Product)</b>	<b>CD4 Count</b>
<b>Intended Use Statement</b>	CD-Chex Plus BC is designed to serve as a quality control specimen for clinical flow-cytometric procedures performed with Beckman Coulter <sup>®</sup> flow cytometry instruments.	CD4 Count is intended to be used as an assayed whole blood quality control for evaluating white blood cell subsets on a flow cytometry instrument
<b>Open Vial Stability</b>	30 days	Same
<b>Closed Vial Stability</b>	90 days	60 days
<b>Reagents</b>	Contains stabilized human blood in a preservative medium.	Same
<b>Storage Conditions</b>	2 - 10°C	Same

**Testing Performed:**

Four studies of CD4 Count were conducted: 1) Run to Run Reproducibility & Whole Blood; 2) Open Vial Stability; 3) Closed Vial Stability; and 4) Alternate Site Testing. Study results showed CD4 Count to be consistently reproducible and stable for the entire product dating.

**Conclusions Drawn from the Tests:**

Study results show CD4 Count to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating. CD4 Count is a safe and effective product, which fulfills its intended use when used as instructed in the product package insert.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Streck Inc.  
c/o Ms. Kerrie Oetter  
Quality Assurance Coordinator  
7002 South 109<sup>th</sup> Street  
Omaha, NE 68128

**FEB 11 2009**

Re: k083926  
Trade/Device Name: CD4 Count  
Regulation Number: 21 CFR 864.8625  
Regulation Name: Hematology Quality Control Mixture  
Regulatory Class: Class II  
Product Code: GGL  
Dated: December 30, 2008  
Received: December 31, 2008

Dear Ms. Oetter:

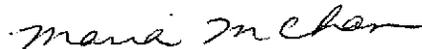
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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" (21 CFR 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): K083926

Device Name: **CD4 Count**

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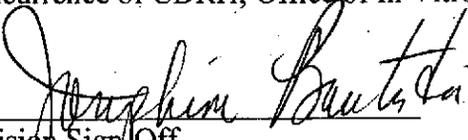
Prescription Use  X   
(21 CFR Part 801 Subpart D)

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)

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

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