K110718

MAY 2 6 2011

510(k) Summary of Safety and Effectiveness

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

Official Correspondent: Deborah Kipp, Quality Assurance Coordinator
(402) 537-5215

Date Prepared: March 14, 2011

Name of Device:
Trade Name: Cell-Chex™ with CPPD Crystals
Common Name: Hematology Control for Body Fluids
Classification Name: Hematology Quality Control Mixture (864.8625)

Predicate Device: Cell-Chex™ (K101335) Manufactured by Streck

Description:
Cell-Chex™ with CPPD Crystals is a stabilized suspension of human red blood cells, human white blood cells and calcium pyrophosphate dihydrate (CPPD) Crystals (Level 1 only) in a preservative medium. The product is packaged in glass vials containing 2.0ml. The closures are polypropylene screw caps with polyethylene liners. There are two different levels. Level 1 contains a low cell count and CPPD crystals, and Level 2 contains a high cell count and no crystals. The vials will be packaged in a six (6) or twelve (12) welled vacuum formed clamshell container with the package insert / assay sheet. The product must be stored at 2 - 10°C.

Intended Use:
Cell-Chex™ with CPPD Crystals is an assayed control intended for monitoring total cell counts performed manually using a hemocytometer to validate quantitation of red and white blood cells in patient cerebrospinal fluid and body fluid samples including pleural, pericardial, peritoneal and synovial fluid. Level 1 contains calcium pyrophosphate dihydrate (CPPD) Crystals which can be used to monitor the presence of crystals in synovial fluid.

Cell-Chex™ with CPPD Crystals is also intended for monitoring white blood cell differentiation (Mononuclear, Polymorphonuclear; Neutrophils, Eosinophils, Basophils, Lymphocytes and Monocytes) in body fluid samples performed using Cytospin® smears.

Comparison to Predicate Device:

	Cell-Chex™ (Predicate Product)	Cell-Chex™ with CPPD Crystals
Intended Use Statement	Cell-Chex™ is an assayed control intended for monitoring total cell counts performed manually using a hemocytometer to validate quantitation of red and white blood cells in patient cerebrospinal fluid and body fluid samples including pleural, pericardial, peritoneal and synovial fluid. Level 1 contains monosodium urate crystals which can be used to monitor the presence of crystals in synovial fluid. Cell-Chex™ is also intended for monitoring white blood cell differentiation (Mononuclear, Polymorphonuclear; Neutrophils, Eosinophils, Basophils, Lymphocytes and Monocytes) in body fluid samples performed using Cytospin® smears.	Cell-Chex™ with CPPD Crystals is an assayed control intended for monitoring total cell counts performed manually using a hemocytometer to validate quantitation of red and white blood cells in patient cerebrospinal fluid and body fluid samples including pleural, pericardial, peritoneal and synovial fluid. Level 1 contains calcium pyrophosphate dihydrate (CPPD) crystals, which can be used to monitor the presence of crystals in synovial fluid. Cell-Chex™ with CPPD Crystals is also intended for monitoring white blood cell differentiation (Mononuclear, Polymorphonuclear; Neutrophils, Eosinophils, Basophils, Lymphocytes and Monocytes) in body fluid samples performed using Cytospin® smears.
Open Vial Stability	30 days	Same
Closed Vial Stability	60 days	Same
Reagents	Stabilized human red blood cells, human white blood cells and monosodium urate crystals (Level 1 only) in a preservative medium.	Stabilized human red blood cells, human white blood cells CPPD crystals (Level 1 only) in a preservative medium.
Storage Conditions	2 - 10°C	Same
The only difference relative to the predicate product (i.e. Cell-Chex™) is the substitution of the inert CPPD crystal component for the inert urate crystals in the Level 1 control. Level 2 contains the same formulation as Cell-Chex™ (K101335). The product composition and the associated product usage applications (i.e. hemocytometer and Cytospin® smears) are unchanged. The CPPD crystal component is intended to be listed on the assay as positive or negative (i.e. present or not present).		

Discussion of Tests and Test Results:

Four types of studies were conducted to establish performance of Cell-Chex with CPPD Crystals. The four tests conducted were Closed Vial Stability, Open Vial Stability, Run-to-Run Reproducibility, and Precision Performance. All testing showed that Cell-Chex™ with CPPD crystals is consistently reproducible, substantially equivalent to the predicate product and stable for the shelf life claimed.

Conclusions Drawn From Tests

Cell-Chex™ with CPPD Crystals fulfills its intended use as a control mixture for manual counting of Red Blood Cells and White Blood Cells in body fluids such as cerebrospinal fluid. Results presented show it is consistently reproducible and performs comparably to the predicate product. Cell-Chex™ with CPPD Crystals is a safe and effective product when used as indicated in the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Streck, Inc.
c/o Ms. Deborah Kipp
Quality Assurance Coordinator
7002 South 109th Street
Omaha, NE 68128

MAY 26 2011

Re: k110718
Trade/Device Name: Cell-Chex™ with CPPD Crystals
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: GLQ
Dated: March 14, 2011
Received: March 15, 2011

Dear Ms. Kipp:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 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

Indications for Use Form

510(k) Number (if known): K110718

Device Name: Cell-Chex™ with CPPD Crystals

Indications For Use:

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Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

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