K042587

OCT 1 9 2004

510(k) Summary of Safety and Effectiveness

510(k) Submitter: Streck Laboratories
7002 South 109th Street
La Vista, NE 68128

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

Date Prepared: September 17, 2004

Names of Device:

Trade Name:	**Retic-Chex for Cell-Dyn®**
Common Name:	Hematology Reagents
Classification Name:	Hematology quality control mixture, 21CFR864.8625

Predicate Device: Retic-Chex® Linearity manufactured by Streck Laboratories, K000115

Description:

Retic-Chex for Cell-Dyn is a suspension of stabilized human red blood cells and simulated human reticulocytes packaged in plastic vials containing 1.0ml volumes. The device consists of two levels of reticulocyte percentage range. Control I reticulocyte percent range will be 1.5 – 2.0. Control II reticulocyte percent range will be 3.9 – 5.8. Closures are injection molded polypropylene screw-top caps. The vials are packaged in vacuum molded clam-shell box.

Intended Use:

Retic-Chex for Cell-Dyn is an assayed control for evaluating the accuracy and precision of automated, semi-automated, and manual methods of reticulocyte counting. It is designed for use on the following automated reticulocyte counting. It is designed for use on the following reticulocyte analyzers: Abbott Cell-Dyn 4000, 3700, 3500, and 3200.

Comparison with Predicate Device:

Like Retic-Chex Linearity, Retic-Chex for Cell-Dyn is a multi-level device intended for validation of reticulocyte analysis on a variety of automated hematology instruments. Both devices contain stabilized human red blood cells and simulated human reticulocytes, which properly mimic human whole blood on the intended use analyzers.

Testing Performed:

Three studies of Retic-Chex for Cell-Dyn were conducted: 1) Closed Vial Stability; 2) Open Vial Stability; and 3) Manual Count Closed Vial Stability. Study results showed Retic-Chex for Cell-Dyn to be consistently reproducible and stable for the entire product dating.

Conclusions Drawn from the Tests:

Study results show Retic-Chex for Cell-Dyn to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating. Retic-Chex for Cell-Dyn 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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 9 2004

Ms. Kerrie Oetter
Quality Assurance Coordinator
Streck Laboratories, Inc.
7002 South 109th Street
La Vista, NE 68128

Re: k042587
Trade/Device Name: Retic-Chex for Cell-Dyn®
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: JPK
Dated: September 17, 2004
Received: September 22, 2004

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., 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

510(k) Number (if known): K042587

Device Name: **Retic-Chex for Cell-Dyn®**

Indications For Use:

Retic-Chex for Cell-Dyn is an assayed control for evaluating the accuracy and precision of automated, semi-automated and manual methods of reticulocyte counting.

Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (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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