

NOV 26 1999

K993126

510(k) Summary of Safety and Effectiveness

510(k) Submitter: Streck Laboratories, Inc
P.O. Box 45625
Omaha, Nebraska 68145

Correspondent: Hal Sornson
R&D Manager

Date Prepared: September 16, 1999

Names of Device:

Trade Name: CD Chex CD 34
Common Name: Immunophenotyping Control
Classification Name: White Cell Control §864.8625

Predicate Device: CD Chex Plus RBC (K960894) manufactured
by Streck Laboratories

Description: CD Chex CD 34 is a stabilized suspension of human placental blood containing red blood cells and white blood cells. It is packaged in glass vials containing 1 ml of product. Closures are polypropylene screw caps. The package contains two vials of a single concentration and an assay sheet stating the expected values.

Intended Use: CD Chex CD 34 is designed as a control sample for evaluating the binding of monoclonal antibody using flow cytometry. It is intended to be used with Becton Dickinson ProCount Progenitor Cell enumeration kit and with systems using ISHAGE protocol for CD 34 stem cell marker.

Comparison with Predicate Device: CD Chex Plus RBC is a an immunophenotyping control for several clinically useful cell surface markers. CD Chex CD 34 is assayed only for the CD 34 marker. They are both procedural controls for monitoring reagents and the instrument.

Discussion of Tests and Test Results: Studies were conducted on three(3) Pilot lots to assess the performance of CD Chex CD 34. These were:
1.) Long term stability, 2) Open vial stability, 3) Within-run and Site to Site reproducibility.
The studies verified that the product performed to specifications and is useful as a control material for CD 34 measurement procedures.

Conclusions Drawn from Tests: CD Chex CD 34 is an effective control for CD 34 immunophenotyping when used according to instructions in the package insert. Extensive raw material testing assures the user of a safe product.

Streck Labs, Inc CD Chex CD 34 510(k)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 26 1999

Mr. Hal Sornson
R & D Manager
Streck Laboratories, Inc.
14124 Industrial Road
Omaha, Nebraska 68144

Re: K993126
Trade Name: CD-Chex CD 34
Regulatory Class: II
Product Code: GGL
Dated: September 16, 1999
Received: September 20, 1999

Dear Mr. Sornson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,

A handwritten signature in cursive script that reads "Steven Gutman".

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K993126/1A1



510(k) Number (if known): K993126

Device Name: CD-Chex CD 34

Indications for Use:

A clinical laboratory performing quantitative stem cell analysis needs a control specimen for verifying the measurement process. CD Chex CD 34 is such a specimen. It consists of stabilized placental blood containing a population of CD 34 positive stem cells. It is used as a procedural control for monitoring monoclonal antibody binding in flow cytometry methods. Users of Becton Dickinson ProCount Progenitor Cell Enumeration Kit or ISHAGE protocol can validate their CD 34 results by controlling the procedure with CD Chex CD 34.

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

Concurrence of CDRH/Office of Device Evaluation (ODE)

[Handwritten Signature]

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K993126

Prescription Use
(Per 21CFR 801.109)

OR

Over-The-Counter Use
(Optional format 1-2-96)

Sep. 24, 1999

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