

JUL 22 1998

510(k) Summary of Safety and Effectiveness

510(k) Submitter: Streck Laboratories, Inc.
14124 Industrial Road
Omaha, Nebraska 68144

K982290

Official Correspondent: Paul Kittelson
Quality Assurance Manager
(402) 691-7465

Date Prepared: June 26, 1998

Names of Device:

Trade Name:	Chem-Chex STAT
Common Name:	Assayed chemistry control
Classification Name:	Multi-analyte control (§862.1660)
Classification Number:	75JJY

Predicate Device: i-STAT control (K934641) manufactured by i-STAT Corp. Chem-Chex STAT control (K96115) manufactured by Streck Laboratory.

Description:

Chem-Chex STAT is a suspension of stabilized mammalian red blood cells in an aqueous buffered medium. Manufactured in three clinically significant levels, it is packaged in dropper tip polyethylene vials containing 2.0 mL volumes. Closures are injection molded polypropylene screw-top caps. Vials are packaged in polystyrene jars.

Intended Use:

Chem-Chex STAT is intended to be used for verifying the accuracy of i-STAT chemistry analyzers used with i-STAT test cartridges. Chem-Chex STAT is assayed for pH, Na⁺, Ca⁺⁺, Cl⁻, K⁺, BUN, Hgb, Hct, and Glucose.

Comparison with Predicate Devices:

Like the i-STAT Control and former Chem-Chex STAT (96115), Chem-Chex STAT (New) is intended to enable the user to verify satisfactory performance of the i-STAT analyzer and cartridge system. All levels of the device are liquid controls containing sodium, chloride, potassium, blood urea nitrogen, and glucose.

Like its predecessor control, Chem-Chex STAT (New) is an assayed control that provides the user a complete positive procedural control. It contains red blood cells and is assayed for hemoglobin and hematocrit, it is not assayed for PCO₂, or PO₂, like the i-STAT.

Discussion of Tests and Test Results:

Three studies of Chem-Chex STAT (New) were conducted: I) lot to lot reproducibility; II) open and closed vial stability; and III) site to site comparisons at 4 different locations. Study results showed Chem-Chex STAT (New) to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating.

Conclusions Drawn from Tests:

Study results show Chem-Chex STAT (New) to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating. Chem-Chex STAT (New) 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

JUL 22 1998

Paul Kittelson
Quality Assurance/Regulatory Affairs Manager
Streck Laboratories, Inc.
14124 Industrial Road
Omaha, Nebraska 68144

Re: K982290
Chem-Chex STAT (New)
Regulatory Class: I
Product Code: JJY
Dated: June 26, 1998
Received: June 29, 1998

Dear Mr. Kittelson:

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 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.

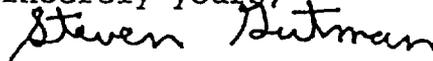
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

510(k) Number (if known): _____

Device Name: Chem-Chex STAT

Indications For Use:

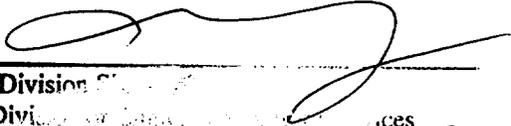
Chem-Chex STAT is intended to be used for verifying the accuracy of of i-STAT chemistry analyzers used with i-STAT test cartridges. Chem-Chex STAT is assayed for Na⁺, Cl⁻, K⁺, BUN, Hgb, Hct, Glucose, pH, and Ca⁺⁺.

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

_____ **Concurrence of CDRH, Office of Device Evaluation (ODE)** _____

Prescription Use
(Per 21 CFR 801.109)

OR



(Division of Medical Devices)
Division of Medical Devices ices
510(k) number: K982290

Over-The-Counter Use _____

(Optional Format 1-2-96)