K051706

AUG 17 2005

510(k) Summary of Safety and Effectiveness

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

Official Correspondent: Carol Thompson, Quality Assurance Manager
(402)-537-5213

Date Prepared: June 14, 2005

Name of Device:
Trade Name: iQ® Body Fluids Control
Common Name: Hematology Control for Body Fluids
Classification Name: White and Red Blood Cell Control (864.8625)

Predicate Device: Cell-Chex (K000076) Manufactured by Streck

Description:
iQ Body Fluids Control is a stabilized suspension of human red blood cells and simulated white blood cells in a solution containing biological salts and anti-microbial preservatives. The product is packaged in glass vials containing 8ml. The closures are polypropylene screw caps with polyethylene liners. Four vials are included in a set. Two vials are level 1 with a low cell count and the other two vials are level 2 with a higher concentration of cells. The vials are further packaged in a six (6) welled vacuum formed "clam-shell" container with the package insert / assay sheet. The product must be stored at 2 – 10° C.

Intended Use:
iQ® Body Fluids Controls are intended for use on iQ® Series analyzers, with the optional iQ® Body Fluids Module installed, as a control for evaluating body fluid RBC and nucleated cell counts. The device will consist of two levels of red blood cells and nucleated cells.

Comparison to Predicate Device:
Like Cell-Chex, iQ Body Fluids Control is an assayed control mixture of red and white blood cells set at specific concentrations. Cell-Chex and iQ Body Fluids Control have a 30 day open vial stability.

Unlike Cell-Chex, iQ Body Fluids Control is used for the Iris Diagnostics' iQ Body Fluids Module. Cell-Chex is used with manual diagnostic methods, and Cell-Chex has a 6 (six) month closed vial stability where iQ Body Fluids Control has a 40 day closed vial stability.

Discussion of Tests and Test Results:
Four types of studies were conducted to establish performance of iQ Body Fluids Control, closed vial stability, open vial stability, alternate site testing, and run to run reproducibility. All testing showed that iQ Body Fluids Control is consistently reproducible and stable for the closed vial stability claim.

Conclusions Drawn From Tests:
iQ Body Fluids Control is a safe and effective product useful for controlling the Iris Diagnositc Body Fluid Module. It will perform as claimed when used in accordance with the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 17 2005

Mr. Mark Lewallen
Quality Assurance Coordinator
Streck
7002 South 109th Street
La Vista, Nebraska 68128

Re: k051706
Trade/Device Name: iQ® Body Fluids Control
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: Class II
Product Code: JPK
Dated: August 10, 2005
Received: August 11, 2005

Dear Mr. Lewallen:

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 (240) 276-0484. 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/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051706

Device Name: iQ® Body Fluids Control

Indications For Use: iQ® Body Fluids Controls are intended for use on iQ® Series analyzers, with the optional iQ® Body Fluids Module installed, as a control for evaluating body fluid RBC and nucleated cell counts. The device will consist of two levels of red blood cells and nucleated cells.

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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