K960894

510(k) Summary of Safety and Effectiveness

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Names of Device:

Trade Name:	CD-Chex PLUS (K960894)
Common Name:	Immunophenotyping control
Classification Name:	White cell control (§864.8625)

Predicate Device: CD-Chex (K920997) manufactured by Streck Laboratories

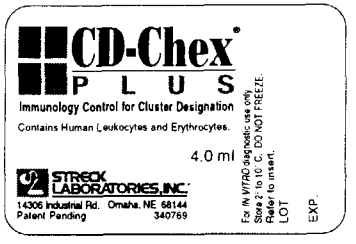
Description: CD-Chex PLUS is a suspension of stabilized human red blood cells and human white cells packaged in glass vials containing 2.5 or 4.0 mL volumes. Closures are polypropylene screw-top caps. The vials are packaged in polystyrene jars.

Intended Use: CD-Chex PLUS is intended to be used as a control for evaluating monoclonal antibody binding by flow cytometry. CD-Chex PLUS control cells possess surface antigens detectable with monoclonal antibodies. When these cells are stained with fluorescent antibodies and analyzed by flow cytometry they provide a reference for normal peripheral blood leukocytes. CD-Chex PLUS is designed for use on Becton Dickinson and Coulter flow cytometry systems

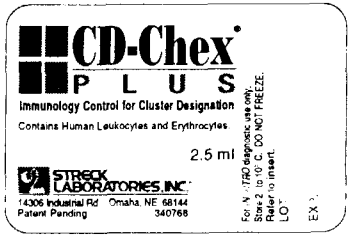
Comparison with Predicate Device: Like CD-Chex, CD-Chex PLUS is intended to enable the user to verify satisfactory performance of flow cytometry systems. Both devices contain control cells which possess surface antigens detectable with monoclonal antibodies. Unlike CD-Chex, CD-Chex PLUS contains stabilized human red cells. This allows the user to verify proper performance of the red cell lysing step which gives the user a true positive procedural control.

Discussion of Tests and Test Results: Four studies of CD-Chex PLUS were conducted: I) Lot to Lot Reproducibility and Comparison to Whole Blood ; II) Site to Site Reproducibility and Comparison to Predicate Device; III) Long Term Stability; and IV) Open Vial Stability. Study results showed CD-Chex PLUS to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating.

Conclusions Drawn from Tests: CD-Chex PLUS is a safe and effective control for immunophenotyping when used as instructed in the product package insert.



4.0 mL Vial Label



2.5 mL Vial Label

Jar Label