Indications for Use and the Summary of Safety and Effectiveness for Special 510(k): Device Modification submission on **Beckman Coulter™ Stem-Kit™ Reagents** (BK040032)

For additional information, contact:

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Section 1C: INDICATIONS FOR USE

510(k) Number (if known): Not assigned

Device: Beckman Coulter™ Stem-Kit™ Reagents

Indications For Use:

INTENDED USE:

Stem-Kit Reagents consist of a two-color fluorescent (FITC, PE) murine monoclonal antibody reagent, a two-color murine fluorescent (FITC, PE) isoclonic control, an absolute count reagent, a cell viability reagent, and a lysing reagent. It is intended "For In Vitro Diagnostic Use", for the simultaneous identification and enumeration of CD45+ and dual-positive CD45+ CD34+ cell population percentages and absolute counts in biological specimens by flow cytometry. Biological specimens include fresh normal or mobilized peripheral whole blood, and fresh or thawed: apheresis products, cord blood and bone marrow. Cell population measurements may be obtained using either an automated method or a manual method for gating and analysis on any appropriately configured flow cytometer.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ **OR** **Over-The-Counter Use_____**
(Per 21 CFR 801.109)

Section 1 D: Summary of Safety and Effectiveness for Stem-Kit Monoclonal Antibody Reagents

1.0 General Information

Device Generic Name(s):	Immunophenotyping monoclonal antibody reagents
Device Trade Name(s):	CD45-FITC / CD34-PE Reagent (45/34) and CD45-FITC/Isoclonic™ Control-PE Reagent Monoclonal Antibody Reagents
Device Classification:	CD45-FITC / CD34-PE Reagent (45/34) and CD45-FITC/Isoclonic™ Control-PE Reagent Monoclonal Antibody Reagents are Class II medical devices.
Applicant Name and Address:	Beckman Coulter, Inc. 11800 SW 147 Avenue Miami, FL 33196-2500
Date:	March 31, 2003

2.0 Legally Marketed Device(s)

stemONE™ System for EPICS® XL™/XL-MCL™ Flow Cytometry Systems

FDA 510(k) Number(s): BK010044

3.0 Device Description

The Stem-Kit Reagents product is comprised of five reagents:

- CD45-FITC / CD34-PE Reagent (45/34)
- CD45-FITC / IsoClonic Control-PE Reagent (45/CTRL)
- Stem-Count Fluorospheres
- 7-AAD Viability Dye
- 10X NH_4Cl Lysing Solution

4.0 Principle of Method:

This test depends on the ability of a monoclonal antibody to bind to the surface of cells expressing discrete antigenic determinants. The CD45-FITC / CD34-PE Reagent in Stem-Kit™ Reagents is a combination of two murine monoclonal antibodies; each conjugated to a specific fluorochrome and specific for a different cell surface antigen. Specific cell surface staining is accomplished by incubating duplicate samples of a biological specimen with the two-color CD45-FITC / CD34-PE reagent. An additional test of the same sample is stained with the CD45-FITC / IsoClonic™ Control-PE Reagent to check the nonspecific binding of the CD34-PE

monoclonal antibody. 7-AAD Viability Dye, a nucleic acid dye that binds to accessible base pairs (cellular DNA), is used to distinguish between viable and nonviable cells. The red blood cells in each sample are lysed with NH_4Cl Lysing Solution prepared as a working dilution, Stem-Count™ Fluorospheres is added, and the remaining cells analyzed by flow cytometry. Process control and quality control, for the assay, are provided by the instrument and sample quality control reagents consisting of Flow-Check™ Fluorospheres, Flow-Set™ Fluorospheres, Stem-Comp™ Reagent, and Stem-Trol™ Control Cells or appropriately validated equivalents.

5.0 Indications for Use:

The Stem-Kit Reagents are designed to identify the human hematopoietic progenitor cells (HPC) using the following criteria: True CD34+ cells (a) express CD34 antigen, (b) express CD45 antigen with staining intensity characteristic of blast cells (i.e., readily detectable but at lower levels than lymphocytes and monocytes), and (c) exhibit low side-angle and low to intermediate forward angle light scatter characteristics of blast cells. Exclusion of dead CD34+ HPC from viable CD34+ HPC enumeration is achieved using the 7-AAD Viability Dye. Biological specimens may include fresh normal or mobilized peripheral whole blood, and fresh or thawed: apheresis products, cord blood and bone marrow.

6.0 Description of the modification:

The currently marketed stemONE™ System for EPICS® XL™/XL-MCL™ Flow Cytometry Systems is an automated analysis method comprising Stem-Kit Reagents, stemONE System software and the EPICS® XL™/XL-MCL™ Flow Cytometry Systems with System II software for "For In Vitro Diagnostic Use" for the simultaneous identification and enumeration of CD45+ and dual-positive CD34 (CD45+/CD34+) cell population percentages and absolute counts. The currently marketed system also provides for manual (standard) analysis on the EPICS® XL™/XL-MCL™ Flow Cytometry Systems with System II software. This premarket notification is to add operator instructions for the use of the five Stem-Kit reagent components of that automated system as a stand alone reagent system on any appropriately configured equivalent flow cytometer system, allowing the operator to manually adjust gating and other operational parameters to optimize results at their discretion.