SECTION 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

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2.0 DATE SUBMITTED: February 14, 2002

3.0 DEVICE NAME:

3.1 Proprietary Name:
stemONE™ System for EPICS® XL™/XL-MCL™ Flow Cytometry Systems

3.2 Common or Usual or Classification Name:
Immunophenotyping System with Reagents, Quality Controls and Software for Flow Cytometry

3.3 Product Classification:
Product Code: GKZ; 21 C.F.R. Section: 864.5220; Panel: Hematology and Pathology Devices; Device Class: II

4.0 PREDICATE DEVICE:

K990172 - tetraONE™ System for EPICS® XL™ Flow Cytometry Systems with Cyto-Stat® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent and Cyto-Stat® tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagent

K962768 - Cyto-Stat® triCHROME CD45-FITC/CD4-RD1/CD3-PC5 Monoclonal Antibody Reagent with Cyto-Stat® triCHROME CD45-FITC/MsIgG1-RD1/MsIgG1-PC5 Isotypic Control

K954688 - Flow-Count™ Fluorospheres

K984216 - Immuno-Trol™ Cells

K964618 - Cyto-Comp™ Reagent Kit and Cyto-Comp™ Cell Kit

K944751 - Flow-Set™ Fluorospheres

5.0 DESCRIPTION OF DEVICE:

The stemONE™ System for EPICS® XL™/XL-MCL™ Flow Cytometry Systems combines a two-color fluorescent monoclonal antibody reagent, isoclonic control, lysing reagent, cell viability reagent, quality control reagents, absolute count reagent, color compensation reagent, and software to provide for both automated and manual gating and analysis of cell populations in biological specimens using EPICS® XL™/XL-MCL™ Flow Cytometry Systems with System II™ Software. Biological specimens include fresh normal or mobilized peripheral whole blood, and fresh or thawed: apheresis products, cord blood and bone marrow.

6.0 INTENDED USE OF DEVICE:

The stemONE™ System is intended "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.

7.0 COMPARISON TO PREDICATE:

The stemONE™ System [stemONE™ System Software, Stem-Kit™ Reagents, Stem-Count™ Fluorospheres, Stem-Trol™ Control Cells, Stem-Comp™ Reagent, Flow-Set™ Fluorospheres] is substantially equivalent to the Beckman Coulter, Inc. Cyto-Stat® tetraCHROME™ SYSYEM for automated gating and analysis, and the Cyto-Stat® triCHROME™ system for manual gating and analysis, of cell populations in biological specimens. The systems are governed by the same regulations, and employ the same or comparable features, principles of operation and techniques for cell identification and enumeration. These include immunophenotyping with fluorescent-labeled monoclonal antibodies and flow cytometry, cell population gating, monitoring and control of non-specific and non-targeted monoclonal antibody binding to irrelevant cell populations, absolute count determination, cell lysing, process and quality control, color compensation and instrument set-up, data acquisition and analysis. The new and predicate systems differ only in terms of the cell populations identified and enumerated and the types of biological specimens that can be used. Gating and analysis of CD34+ cell populations follows ISHAGE-recommended guidelines. The automated method requires stemONE™ System Software and is designed to simplify flow cytometric analysis by increasing automated modes of operation and the accuracy, precision and reliability of results. The manual method does not require this software. The monoclonal antibody and isoclonic control reagents in Stem-Kit™ Reagents are conjugated to fluorescein isothiocyanate (FITC) and phycoerythrin (PE).

8.0 SUMMARY OF PERFORMANCE DATA:

Product testing to assess performance of the automated and manual methods of the stemONE™ System is described below. Studies were designed in line with instructions for use given in the product labeling and performance specifications. Results demonstrated that the stemONE™ System met all performance specifications and provided appropriate values for CD45+ and dual-positive CD34 (CD45+/CD34+) cell population absolute counts and percentage. [NOTE: CD45+ and CD34+ were expressed as absolute count (cells/μL); CD34 percentage (%) was expressed in terms of percentage of the total leukocyte count.]

8.1 Expected Values for Reference Ranges:

Normal whole blood specimens (n=117) were collected from a population of males (n=58) and females (n=59) to establish a reference range. Replicate tests for each specimen were prepared according to the Stem-Kit™ Reagents package insert and analyzed on EPICS® XL™/XL™-MCL flow cytometers using automated and manual gating and analysis to obtain the CD45+, CD34+, and CD34% values.

Results were analyzed in terms of minimums, maximums, and means ± 1 SD.

8.2 Linearity:

Replicate measurements were made at each of 10 serial dilutions for CD34+ spiked and fresh mobilized peripheral whole blood specimens to achieve a dynamic range (0 to 2,000 cells/μL) and a low-end sensitivity range of (0 to 150 cells/μL), respectively, of CD34+ cell concentrations. Samples were prepared according to the Stem-Kit™ Reagents package insert and analyzed on EPICS® XL™/XL™-MCL flow cytometers.

Results were analyzed in terms of linear regression analyses for expected versus recovered absolute count for the mean of the replicates less endogenous CD34+ cells and demonstrated Linearity of the assay.

8.3 Accuracy of Method:

The degree of accuracy for the automated and manual methods of the stemONE™ System was studied at four sites using CD34+-spiked fresh normal peripheral whole blood, fresh peripheral whole blood (n=59 from three sites), fresh apheresis products (n=51 from three sites), fresh cord blood (n=29 from two sites), fresh bone marrow (n=33 from two sites), thawed apheresis products (n=23 from one site), thawed cord blood (n=31 from two sites), and thawed bone marrow (n=20 from one site). The specimens were prepared according to the Stem-Kit™ Reagents package insert and analyzed on EPICS® XL™/XL™-MCL flow cytometers using automated and manual gating and analysis to obtain the CD45+, CD34+, and CD34% values.

Results were analyzed in terms of minimums, maximums, means ± 1 SD, CVs, confidence intervals and regression analyses and demonstrated Accuracy of Method for the automated method and the manual method of the assay.

8.4 Precision (Interlaboratory):

Specimens were obtained with low (fresh mobilized peripheral blood), mid-range (apheresis products) and high (apheresis products) levels of CD34+ cells covering a dynamic range (0 to 2,000 cells/μL). In a parallel assay, three individual technologists prepared sets of 10 samples for each of the three levels according to the Stem-Kit™ Reagents package insert. The samples were analyzed on three different EPICS® XL™/XL™-MCL flow cytometers using automated and manual gating and analysis to obtain the CD45+, CD34+, and CD34% values.

Results were analyzed in terms of mean ± 1 SD and CV and demonstrated Interlaboratory Precision and Site Reproducibility for the assay.

8.5 Precision (Intralaboratory):

Specimens covering a dynamic range (0 to 2,000 cells/μL) were obtained by using fresh peripheral whole blood, fresh and thawed apheresis products and cord blood, and fresh bone marrow from four evaluation sites. Ten samples from each were prepared according to the Stem-Kit™ Reagents package insert and analyzed on EPICS® XL™/XL™-MCL flow cytometers using automated and manual gating and analysis to obtain the CD45+, CD34+, and CD34% values.

Results were analyzed in terms of mean ± 1 SD and CV and demonstrated Intralaboratory Precision for the assay.

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS:

This document is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.