510(k) Summary for the
Stem-Kit Reagents and stemCXP SYSTEM

510(k) Owner / Submitter Information

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Device Information

Trade Name: a) Stem-Kit Reagents, b) stemCXP SYSTEM for the FC 500 with CXP Software
Common Name: a) Stem-Kit Reagents, b) stemCXP
Classification Name: a) Immunophenotyping monoclonal antibody reagents (21 CFR 864.5220), b) Hematology and Pathology Devices (21 CFR 864.5220)
Classification: Class II
Product Code: GKZ
Panel: Hematology

Predicate Device Information

Predicate Product	510(k) Number	Date Cleared	Classification	21 CFR	Product Code
Stem-Kit Reagents	BK040032	May 5, 2004	Class II	864.5220	GKZ
stemCXP SYSTEM	BK040055	Sept 16, 2004	Class II	864.5220	GKZ

OVERVIEW

Stem-Kit Reagents and stemCXP SYSTEM

This special 510(k) submission pertains to the labeling of the Stem-Kit Reagents part number IM3630 and stemCXP SYSTEM part number 627260.

The Stem-Kit Reagents (FDA cleared BK040032) are used to prepare samples for the identification and enumeration of viable CD34+ cells (hematopoietic stem cells) in normal or mobilized peripheral blood, apheresis products, bone marrow, and cord blood. It is intended for the simultaneous identification and enumeration of CD45+ and dual-positive CD45 CD34+ cell population percentages and absolute counts. The testing is performed on a flow cytometer equipped with a 488 nm laser and optical configuration to detect the multiple color antibodies in the Stem-Kit reagents. The Cytomics FC 500 flow cytometer (CXP Software), the Stem-Kit Reagents and the stemCXP software are FDA cleared (BK040055) as a system.

The Stem-Kit Reagents product is comprised of the reagents listed below:

- CD45-FITC / CD34 PE and CD45-FITC/ lsoclonic Control-PE monoclonal antibody reagents. Each monoclonal antibody reagent is a liquid mixture of two murine monoclonal antibodies. Each antibody in the reagent is labeled with a different fluorochrome.

- 7-Amino Actinomycin D dye (7-AAD) Viability dye is a chemical solution stain used to identify nonviable cells by flow cytometric analysis.

- Stem-Count Fluorospheres or Flow-Count Fluorospheres is an assayed suspension of fluorescent microspheres used to determine absolute counts directly on a flow cytometer.

- NH_4CI Lysinq Solution is provided as a 10X concentrated, 20 mL solution. It contains a mixture of ammonium chloride (NH_4CI), potassium bicarbonate ($KHCO_2$), Disodium Ethylene Diamine Tetra acetic Acid (EDTA).

Cytomics FC 500 Flow Cytometry Systems

FC 500 flow cytometry systems apply the principles of flow cytometry to analyze a stained and lysed whole blood sample to identify various cellular populations determined by the specific monoclonal antibodies and fluorochromes used.

The stemCXP SYSTEM Software is used with the Stem-Kit Reagents on the FC 500 flow cytometry systems for automated analysis.

Manual Gating Protocol

A manual gating protocol method may also be utilized with the Stem-Kit Reagents; this method does not make use of the stemCXP software. The Stem-Kit Reagents instructions for use provide the steps to create the protocols to acquire and analyze the prepared samples manually.

Intended Use/Indications for 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. Refer to this Stem-Kit Reagents package insert for complete instructions if using the manual method. Refer to the stemCXP System Guide provided with the stemCXP for complete instructions if using the automated method.

The stemCXP SYSTEM, comprised of stemCXP Software for FC 500 flow cytometry systems with CXP software, Stem-Kit Reagents, quality control and standardization reagents, provides automated analysis of cell populations in fresh peripheral or mobilized peripheral whole blood, fresh bone marrow, and fresh or thawed apheresis products and cord blood. The stemCXP SYSTEM is intended for In Vitro Diagnostic Use to simultaneously identify and enumerate CD45+ and CD45+/CD34+ dual positive cell populations.

Design Change Description:

The Stem-Kit Reagents Instructions for Use Specimen Handling, Specimen Requirements and the stemCXP SYSTEM guide, Storage Conditions and Stability will be updated from the current claim to the revised claim as stated in Table 1 below.

Table 1: Current and Revised Storage Claims

Sample	Current IFU Storage Conditions		Revised Storage Conditions	
	Specimen stability	**Prepared sample stability**	**Specimen stability**	**Prepared sample stability**
Whole Blood	24 hours at room temperature (18-25°C)	1 hour stored on ice	**20 hours** at room temperature (18-25°C)	**45 minutes** stored on ice
Mobilized Whole Blood				
Apheresis			24 hours at **2-8°C**	1 hour stored on ice (No change)
Bone Marrow				
Cord Blood	24 hours at room temperature (18-25°C)	1 hour stored on ice	24 hours at room temperature (18-25°C) (No Change)	1 hour stored on ice (No Change)

COMPARISON TO PREDICATE

The design change applied serves as an additional mitigation to an existing risk control measure to the potential failure mode identified in the root cause analysis of the field action that initiated these changes.

Device Comparison Table:

Characteristic	**stemCXP System BK040055** **Stem-Kit Reagents BK040032** **(Predicate)**	**Proposed Device**
Intended Use	Enumeration of CD34+ hematopoietic progenitorcells	Same
Analysis Reagents	Stem-Kit Reagent components: IOT CD45-FITC/CD34 CD45-FITC / lsoclonicControl-PE 7-AAD Viability Dye 10X NH4CL	Same
Auto Compensation Reagents	QuickCOMP 2 Kit	Same

Characteristic	stemCXP System BK040055 Stem-Kit Reagents BK040032 (Predicate)	Proposed Device
AutoSetup Reagents	Flow-Set Fluorospheres,Flow-Check Fluorospheres	Same
QC Reagents	Stem-Trol Control Cells	Same
Absolute Count Reagent	Stem-Count or Flow Count Fluorospheres	Same
Flow Cytometer	Cytomics FC 500 flow cytometry system	Same
System Software	CXP (WINDOWS-based)	Same
Automated Analysis Algorithm	stemCXP Algorithm	Same

Summary of Performance Testing:

Based on the design change scope, testing was limited to specimen and prepared sample stability following CLSI EP 25-A:2009 Evaluation of Stability of In Vitro Diagnostic Reagents, 1st Edition. This design change does not impact the intended use or performance claims of the Stem-Kit Reagents and the stemCXP SYSTEM.

Design Control Activities

The design development and verification/validation of the device modification have been performed under design control. The design control activities were based on risk analysis, and acceptance criteria were set to maintain the efficiency and safety of the device.

Substantial Equivalence Conclusion to Demonstrate Safety, Effectiveness & Equivalent Performance to Predicate:

The updates to the Stem-Kit Reagents and stemCXP labeling that are the subject of this submission, do not change the intended use, nor add or delete a contraindication for the device. The changes do not alter the device control mechanism, operating principle, energy type, environmental specification, ergonomics of the user interface, dimensional specifications, nor packaging. The device is not subject to sterilization.

In summary, it can be concluded that the updated Stem-Kit Reagents with stemCXP SYSTEM, as described in this submission are equivalent in terms of safety and effectiveness to the predicate device.

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