

**Section 1 D: 510(k) Summary of Safety and Effectiveness for
stemCXP SYSTEM for the FC 500 with CXP Software**

1.0 General Information

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Device Trade Name(s): stemCXP SYSTEM for the FC 500 with CXP Software
Device Generic Name(s): Automated differential cell counter

Device Classification: The stemCXP SYSTEM for the FC 500 with CXP Software is a Class II medical device.

2.0 Predicate Device

The stemCXP SYSTEM for the FC 500 with CXP Software claims substantial equivalence to the stemONE SYSTEM for EPICS XL Flow Cytometry Systems.

FDA 510(k) Number(s): BK010044

3.0 Device Description

stemCXP SYSTEM for the FC 500 with CXP Software consists of Stem-Kit, quality control reagents and automated application and operating software on the FC 500 Flow Cytometer.

4.0 Principle of Method:

This test depends upon the ability of a monoclonal antibody to bind to the surface of cells expressing discrete antigenic determinants. Specific cell staining is accomplished by incubating whole blood with monoclonal antibody reagent. Red blood cells are first lysed and the remaining white cells are analyzed on the FC500 flow cytometry systems with CXP operating software and the stemCXP SYSTEM (reagent application) software packages. The stemCXP SYSTEM reagent application software, in conjunction with CXP operating system software, Stem-Kit two-color CD45-FITC/CD34-PE Monoclonal Antibody Reagent and 7-AAD Viability dye, provides automated analysis of hematopoietic progenitor (CD34+ HPC) subpopulations.

5.0 Comparison to Predicate

Comparison	Characteristic	stemONE System for EPICS XL Flow Cytometry System (Predicate)	stemCXP System for the Cytomics FC500 with CXP Software
Similarities	Intended Use	Enumeration of CD34+ hematopoietic progenitor cells	Same as stemONE
	Analysis Reagents	IOT CD45-FITC/CD34 CD45-FITC / Isoclonic Control-PE 7-AAD Viability Dye	Same as stemONE
	AutoSetup Reagents	Flow-Set™ Fluorospheres Stem-Kit Reagents	Same as stemONE
	QC Reagents	Stem-Trol Control Cells	Same as stemONE
Differences	Flow Cytometer	EPICS® XL-MCL™ flow cytometry system	FC500 flow cytometry system
	System Software	System II (DOS-based)	CXP (WINDOWS-based)
	AutoSetup Reagents	Stem-Comp Reagent Kit	QuickCOMP 2 Kit
	Automated Analysis Algorithm	stemONE algorithm	stemCXP algorithm
	Absolute Count Reagent	Stem-Count	Stem-Count or Flow-Count

6.0 Indications for Use:

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.

7.0 Conclusion:

The stemCXP SYSTEM for the FC 500 flow cytometry systems is substantially equivalent to the previously cleared stemONE System for EPICS XL Flow Cytometry System.