510(k) Summary

This 510(k) summary is being provided in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Date of Summary: October 22, 2021

Submitted By

BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807 USA

Contact: Jennifer Karafin
Regulatory Affairs Specialist
Telephone: (315)447-6522
Fax: (408)954-2347
Email: jennifer.karafin@bd.com

Device

Trade Name/Device Name: BD® Stem Cell Enumeration Kit
Classification: Class II
Device Classification: Flow Cytometric Reagents and Accessories
Regulation Description: Automated Differential Cell Counter
Regulation Medical Specialty: Hematology
Product Code: OYE
Regulation Number: 21 CFR 864.5220

Predicate Device

Trade Name/Device Name: BD Stem Cell Enumeration Kit
510(k) Number: BK110037
Classification: Class II
Device Classification: Flow Cytometric Reagents and Accessories
Regulation Description: Automated Differential Cell Counter
Regulation Medical Specialty: Hematology
Product Code: OYE
Regulation Number: 21 CFR 864.5220

Device Description

BD Stem Cell Enumeration (SCE) Kit is a direct immunofluorescence-based three-color flow cytometric in vitro diagnostic assay. The purpose of this 510(k) is to add use of the cleared SCE Kit with BD FACSLyric flow cytometer.

To use SCE Kit on FACSLyric system, the following system components are required:

- SCE Kit
- FACSLyric flow cytometer system
- SCE Assay Module
- BD Stem Cell Control
- BD FACSLink (optional)
- Workstation bundle
- Barcode reader (optional)

To enable use of SCE Kit with FACSLyric system, SCE Assay Module has been created, and SCE assay compatibility has been added to FACSLink.

Indications for Use

The BD® Stem Cell Enumeration Kit is intended for enumeration of viable dual-positive CD45+/CD34+ hematopoietic stem cell populations to determine absolute counts (cells/µL) of viable CD34+ and the percentages of viable CD45+/CD34+ hematopoietic stem cells (%CD34). The following cellular-based products (specimens) can be analyzed with this kit:

- Normal and mobilized peripheral blood
- Fresh and thawed leukapheresis products
- Fresh and thawed bone marrow
- Fresh and thawed cord blood

The kit is intended for in vitro diagnostic (IVD) use on any of the following flow cytometer systems:

- BD FACSLyric™ flow cytometer using BD FACSuite™ Clinical application
- BD FACSCanto™ II flow cytometer using BD FACSCanto™ clinical software
- BD FACSCalibur™ flow cytometer using BD CellQuest™ or BD CellQuest™ Pro software

Substantial Equivalence Comparison between Subject and Predicate Devices

SCE Kit (BK110037) is the predicate device and was cleared on October 19, 2011 for use with FACSCalibur and FACSCanto II flow cytometers. In this submission, SCE Kit (subject device) for use with FACSLyric flow cytometer is compared with SCE Kit (predicate device) for use with FACSCanto II flow cytometer. A comparison of the similarities and differences between the subject device and the predicate device is presented in Table 5-1.

Table 1 Comparison Between Subject and Predicate Device

Feature/Attribute	Subject Device **BD Stem Cell Enumeration Kit (for use with BD FACSLyric Flow Cytometer)**	Predicate Device **BD Stem Cell Enumeration Kit (for use with BD FACSCanto II Flow Cytometer)**	Comments
Device Classification and Product Code	• Regulation Description: Automated Differential Cell Counter • Regulatory Class: II • Regulation Number: 21 CFR 864.5220 • Product Code: OYE		Same Note: BK110037 was originally cleared under product code GKZ. However, FDA later changed this product code to OYE.
Intended Use/ Indications for Use	BD® Stem Cell Enumeration Kit The BD® Stem Cell Enumeration Kit is intended for enumeration of viable dual-positive CD45+/CD34+ hematopoietic stem cell populations to determine absolute counts (cells/µL) of viable CD34+ and the percentages of viable CD45+/CD34+ hematopoietic stem cells (%CD34). The following cellular-based products (specimens) can be analyzed with this kit: • Normal and mobilized peripheral blood • Fresh and thawed leukapheresis products • Fresh and thawed bone marrow • Fresh and thawed cord blood The kit is intended for in vitro diagnostic (IVD) use on any of the following flow cytometer systems: • **BD FACSLyric™ flow cytometer using BD FACSuite™ Clinical application** • BD FACSCanto™ II flow cytometer using BD FACSCanto™ clinical software	BD® Stem Cell Enumeration Kit The BD™ Stem Cell Enumeration (SCE) kit provides simultaneous enumeration of viable dual-positive CD45+/CD34+ hematopoietic stem cell populations in CD34+ absolute counts (cells/µL) as well as the percentage of the total viable leucocyte count that is CD34+ (%CD34). The following specimens can be analyzed with this kit: normal and mobilized peripheral blood, fresh and thawed leucopheresis products, fresh and thawed bone marrow, and fresh and thawed cord blood. The kit is intended for in vitro diagnostic (IVD) use on either a BD FACSCalibur™ flow cytometer using BD CellQuest™ or BD CellQuest™ Pro software or a BD FACSCanto™ II flow cytometer using BD FACSCanto™ software.	Subject device intended use reflects the addition of SCE Kit use with FACSLyric flow cytometer using FACSuite Clinical application. The remaining intended use statement was updated with a clearer and more concise description. The context remains the same.

Feature/Attribute	Subject Device BD Stem Cell Enumeration Kit (for use with BD FACSLyric Flow Cytometer)	Predicate Device BD Stem Cell Enumeration Kit (for use with BD FACSCanto II Flow Cytometer)	Comments
	• BD FACSCalibur™ flow cytometer using BD CellQuest™ or BD CellQuest™ Pro software		
Reagents	BD Stem Cell Enumeration Kit • CD45 FITC/CD34 PE reagent • 7-aminoactinomycin-D (7-AAD) reagent • Ammonium chloride lysing solution • BD Trucount tubes		Same
Detection and Assay Principle	The single-tube assay is performed by staining the sample with the reagent in individual BD Trucount™ tubes for absolute counts. When a sample is added to the reagent, the fluorochrome-labeled antibodies in the reagent bind specifically to the cell surface. Additionally, the lyophilized pellet in the BD Trucount™ tubes dissolves, releasing a known number of fluorescent beads. The dye 7-AAD is added to assess viability of the cells. Cells that are 7-AAD+ are not viable. Ammonium chloride is added to lyse erythrocytes before the sample is acquired on a flow cytometer. During analysis of the sample, the concentration of viable CD34+ cells and viable CD45+ cells, and the percentage of viable CD34+ cells in the viable CD45+ cell population, are calculated.		Same
Specimen Type	• Normal and mobilized peripheral blood collected with either EDTA, ACD-A, heparin, or CPD anticoagulants • Fresh and thawed leukapheresis products collected with a mixture or single source of EDTA, ACD-A, or heparin anticoagulants • Fresh and thawed bone marrow collected with either EDTA, ACD-A, or heparin anticoagulants	Normal and mobilized peripheral blood, fresh and thawed leukapheresis products, fresh and thawed bone marrow, and fresh and thawed cord blood. The following anticoagulants have been verified for use with this assay: • EDTA, ACD-A, heparin, and CPD.	Same specimen types. Anticoagulants for every specimen type are specified for the subject device.

Feature/Attribute	Subject Device **BD Stem Cell Enumeration Kit (for use with BD FACSLyric Flow Cytometer)**	Predicate Device **BD Stem Cell Enumeration Kit (for use with BD FACSCanto II Flow Cytometer)**	Comments
	• Fresh and thawed cord blood collected with either EDTA, ACD-A, heparin, or CPD anticoagulants	• For leukapheresis, a mixture of ACD-A, heparin, and EDTA can also be used.	
Sample Volume	100 µL per test		Same
Instrument and Software Platform	**<u>For FACSLyric flow cytometer:</u>** • **FACSLyric flow cytometer using FACSuite Clinical application with Stem Cell Enumeration (SCE) Assay Module**	<u>For FACSCanto II flow cytometer:</u> • FACSCanto II flow cytometer using FACSCanto clinical software with Stem Cell Enumeration (SCE) Module	Both FACSLyric and FACSCanto II utilize assay module and clinical software that enables instrument setup, assay setup, sample acquisition and analysis for Stem Cell Enumeration assay.
Instrument Configuration	**<u>For FACSLyric flow cytometer:</u>** • **Equipped to detect forward scatter, side scatter and up to six fluorescence channels for IVD use (up to an additional six fluorescence channels are RUO).** • **BD Trucount absolute counting beads are measured in the 527/32 filter and 507 LP mirror or the 586/42 filter and 560 LP mirror.** • **For 7-AAD viability dye monitoring, a 700/54 filter and a 665 LP mirror are used.**	<u>For FACSCanto II flow cytometer:</u> • Equipped to detect forward scatter, side scatter and four fluorescence channels for IVD use (up to an additional four fluorescence channels are RUO). • BD Trucount absolute counting beads are measured with the 530/30 filter and 502 LP mirror or 585/42 filter and 556 LP mirror • For 7-AAD viability dye monitoring the 670 LP filter and 655 LP mirror are used.	Both FACSLyric and FACSCanto II have multiple different configurations. Both FACSLyric and FACSCanto II use a 488-nm laser for SCE Kit. The filters and mirrors used in each of the three channels used for detecting Trucount beads and the 7-AAD dye are very similar.

Feature/Attribute	Subject Device BD Stem Cell Enumeration Kit (for use with BD FACSLyric Flow Cytometer)	Predicate Device BD Stem Cell Enumeration Kit (for use with BD FACSCanto II Flow Cytometer)	Comments
Sample Preparation	Manual		Same
Specimen Stability (Age of Blood/AOB)	• Normal Peripheral Blood: Stain specimens within 24 hours of collection • Mobilized Peripheral Blood: Stain specimens within 24 hours of collection • Fresh Leukapheresis Products: Stain specimens within 24 hours of collection • **Fresh Cord Blood:** **Stain specimens within 48 hours of collection** • Fresh Bone Marrow: Stain specimens within 24 hours of collection • **Thawed Leukapheresis Products:** **Stain immediately after thawing** • **Thawed Cord Blood:** **Stain immediately after thawing** • **Thawed Bone Marrow:** **Stain immediately after thawing**	Stain specimens within 24 hours of collection	The subject device specifies specimen stability for every specimen type. The only difference from the predicate device is the extension of Fresh Cord Blood stability from 24 hours to 48 hours, and the thawed specimens are to be stained immediately. All other fresh sample types remain the same regarding the age of blood.
Stained Sample Stability (Age of Stain/AOS)	• Fresh Leukapheresis Products: Acquire within 1 hour of lysing • Mobilized Peripheral Blood: Acquire within 1 hour of lysing • Fresh Normal Peripheral Blood:	Acquire within 1 hour of lysing	The subject device specifies the stain sample stability for every stained sample type and thawed samples to be acquired immediately.

Feature/Attribute	Subject Device **BD Stem Cell Enumeration Kit (for use with BD FACSLyric Flow Cytometer)**	Predicate Device **BD Stem Cell Enumeration Kit (for use with BD FACSCanto II Flow Cytometer)**	Comments
	Acquire within 1 hour of lysing • Fresh Cord Blood: Acquire within 1 hour of lysing • Fresh Bone Marrow: Acquire within 1 hour of lysing • **Thawed Leukapheresis Products:** **Acquire immediately post-lysis** • **Thawed Cord Blood:** **Acquire immediately post-lysis** • **Thawed Bone Marrow:** **Acquire immediately post-lysis**		
Number of Tubes per Assay	1 Tube		Same
Measurement Range	For FACSLyric flow cytometer: CD34+ cells: **1** – 1,000 cells/µL	For FACSCanto II flow cytometer: CD34+ cells: 0 – 1,000 cells/µL	The measurement range for SCE Kit on FACSLyric flow cytometer is slightly shorter than on FACSCanto II.
Results Reporting	Software-assisted report generation		Same
Reports	For FACSLyric flow cytometer: • Assay Setup Report (Stem Cell Control/Stem Cell + 7-AAD) • Stem Cell Control Lab Report • Stem Cell + 7-AAD Lab Report • **Stem Cell + 7-AAD Physician Report**	For FACSCanto II flow cytometer: • Assay Setup Report (Stem Cell Control/Stem Cell + 7-AAD) • Stem Cell Control Lab Report: • Stem Cell + 7-AAD Lab Report	Subject device has an additional physician report which is a streamlined summary of the lab report without plots and contains cell population parameters only.

The subject device is the same as the predicate device as follows:

- Same indications for use: to enumerate viable dual-positive CD45+/CD34+ hematopoietic stem cell populations to determine absolute counts (cells/µL) of viable CD34+ and the percentages of viable CD45+/CD34+ hematopoietic stem cells (%CD34).
- Same SCE Kit.
- Same assay principle.
- Same specimen types, cell populations for acquisition, and sample preparation method.

The subject device differs from the predicate device as follows:

- FACSLyric flow cytometer has been added for use with the subject device.
- A new assay module (SCE Assay Module) has been created to enable SCE Kit to be used with FACSuite Clinical application on FACSLyric flow cytometer.
- A physician report has been created for FACSLyric.
- Age of blood (AOB) has been extended for fresh cord blood from 24 hours to 48 hours; thawed leukapheresis products, thawed cord blood, and thawed bone marrow are recommended to be stained immediately after thawing and acquired immediately post-lysis.
- Anticoagulants for every specimen type are specified for the subject device.

5.7 Performance Data

The following bench (Table 5-2) and clinical (Table 5-3) performance studies were conducted to support the substantial equivalency determination.

Table 5-2 Bench Performance Summary

Study	Standard	Objective	Results
Within-Site Precision Using Control Materials	*CLSI EP05-A3*	To evaluate the within-site precision of SCE Kit used with FACSLyric flow cytometer.	All acceptance criteria were met.
Repeatability Using Clinical Specimens	*CLSI EP05-A3*	To verify repeatability performance of SCE Kit used with FACSLyric flow cytometer through testing clinical specimens.	All acceptance criteria were met.
Linearity	*CLSI EP06-A*	To evaluate the linear ranges of viable CD34+ and total CD45+ using SCE Kit with FACSLyric flow cytometer.	The linear ranges of viable CD34+ and total CD45+ using SCE Kit with FACSLyric flow cytometer were established based on the acceptance criteria.

Study	Standard	Objective	Results
Sample and Reagent Carryover	*CLSI H26-A2* *CLSI H44-A2*	To evaluate sample and reagent carryover using SCE Kit with FACSLyric flow cytometer.	All acceptance criteria were met.
Analytical Sensitivity	*CLSI EP09c* *CLSI EP05-A3*	To evaluate the analytical sensitivity of SCE Kit with FACSLyric flow cytometer.	All acceptance criteria were met.
Limit of Blank (LoB)	*CLSI EP17-A2*	To evaluate Limit of Blank (LoB) of SCE Kit with FACSLyric flow cytometer.	A LoB of 0 cells/µL for viable CD34+ was achieved.
Interfering Substances	*CLSI EP07-A3* *CLSI EP37-A1*	To evaluate the accuracy of SCE Kit with FACSLyric flow cytometer in the presence of interfering factors.	There was no detectable interference at the tested concentrations. All acceptance criteria were met.
Specimen Stability, Fresh Bone Marrow	*CLSI EP25-A* *CLSI H42-A2*	To verify specimen stability claims for fresh bone marrow.	The test results met the acceptance criteria and supported the specimen stability claims.
Instrument Optical Configuration Equivalency with SCE Assay	*CLSI EP09c*	To verify performance equivalency across multiple configurations of FACSLyric flow cytometer using SCE Kit.	All acceptance criteria were met.

Table 5-3 Clinical Performance Summary

Study	Standard	Testing Approach	Results
Method Comparison	*CLSI EP09c*	To evaluate performance equivalency between SCE Kit (subject device) using FACSLyric flow cytometer, and SCE Kit (predicate device) using FACSCanto II flow cytometer.	A total of 564 enrolled specimens were tested across 5 sites. 63 samples were non-evaluable. The acceptance criteria were met.
Inter-Site Reproducibility	*CLSI EP05-A3*	To evaluate inter-site reproducibility of SCE Kit for use with FACSLyric flow cytometer.	The results demonstrated that the variability across three sites, and results met the acceptance criteria.
Reference Interval	*CLSI EP28-A3c*	To establish the reference intervals of normal peripheral blood using SCE Kit on FACSLyric flow cytometer.	Reference intervals for SCE Kit with FACSLyric flow cytometer were established.
Specimen Stability, Fresh Leukapheresis Products and Fresh Cord Blood	*CLSI EP25-A* *CLSI H42-A2*	To verify specimen stability claims for fresh leukapheresis products and fresh cord blood.	The test results met the acceptance criteria and supported the specimen stability claims.

Conclusion

SCE Kit (subject device) for use with FACSLyric flow cytometer is substantially equivalent to SCE Kit (predicate device) for use with FACSCanto II flow cytometer.