ATTACHMENT 36 – 510(k) SUMMARY

This 510(k) summary is being provided in accordance with the requirements of 21 CFR 807.92.

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1. Submitted By

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2. Device

Trade Name/Device Name:	BD Leucocount™ Kit; BD FACSuite™ Clinical BD Leucocount™ Assay Module; BD FACSLyric™ Flow Cytometer
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

3. Predicate Device

Predicate

Trade Name/Device Name:	BD FACSVia™ System with BD Leucocount™ Reagent Assay
510(k) Number:	BK150307
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

Trade Name/Device Name:	BD FACSLyric™ Flow Cytometer
510(k) Number:	K201814
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

4. Device Description

BD Leucocount™ Kit is a flow cytometric in vitro diagnostic assay based on a nucleic acid fluorescent dye. The purpose of this 510(k) is to add use of the cleared BD Leucocount™ Kit with the BD FACSLyric™ flow cytometer system.

In addition, the intended use statement of the BD FACSLyric™ Flow Cytometer will be updated to support use with the BD Leucocount™ Kit.

To use the BD Leucocount™ Kit on the BD FACSLyric™ flow cytometer system, the following system components are required:

- BD Leucocount™ Kit
- BD Leucocount™ Assay Module for BD FACSuite™ Clinical application
- BD FACSLyric™ flow cytometer system
- BD Leucocount™ RBC Control, BD Leucocount™ PLT Control, or BD Leucocount™ Combo Control
- BD FACSLink™ (optional)

To enable use of the BD Leucocount™ Kit with the BD FACSLyric™ flow cytometer system, BD Leucocount™ Assay Module has been developed.

5. Indications for Use

BD Leucocount™ Kit
The BD Leucocount™ Kit consists of BD Leucocount™ Reagent (propidium iodide fluorescent dye) and BD Trucount™ Tubes and is intended for use with the BD FACSCalibur™, BD FACSort™, BD FACScan™, BD FACSVia™, and BD FACSLyric™ flow cytometer systems, or for a flow cytometer equipped with a 488-nm laser able to threshold on propidium iodide fluorescence, for enumerating residual white blood cells (rWBCs) in leucoreduced blood products.

For in vitro diagnostic use.

BD FACSLyric™ Flow Cytometer
The BD FACSLyric™ flow cytometer is intended for use as an in vitro diagnostic device for the following:

- Immunophenotyping using up to six fluorescence detection channels and two light scatter channels using a blue (488-nm) and a red (640-nm) laser.
- Enumeration of residual white blood cells (rWBCs) in leucoreduced blood products.

It is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.

6. Substantial Equivalence Comparison between Subject and Predicate Devices

Table 1 provides a summary list of the subject devices and their corresponding predicate device.

Table 1. Subject and Predicate Devices

Subject Device	**Predicate Device**
BD Leucocount™ Kit (with BD FACSuite™ Clinical BD Leucocount™ Assay Module)	BD FACSVia™ System with BD Leucocount™ Reagent Assay (BK150307)
Subject Device	**Predicate Device**
BD FACSLyric™ Flow Cytometer	BD FACSLyric™ Flow Cytometer (K201814)

BD Leucocount™ Kit – Summary of Device Comparison
Table 2 provides a comparison between the subject BD Leucocount™ Kit and its predicate device.

The subject BD Leucocount™ Kit is the same as its predicate device, as follows:

- Same indications for use: for enumerating residual white blood cells in leucoreduced blood products.
- Same components in the BD Leucocount™ Kit (BD Leucocount™ Reagent and BD Trucount™ Tubes).
- Same assay principle.
- Same specimen types, specimen stability, cell population for analysis, and sample preparation method.

The subject BD Leucocount™ Kit differs from its predicate device, as follows:

- BD FACSLyric™ Flow Cytometer has been added for use with the subject device.
- An assay module (BD Leucocount™ Assay Module) has been developed to enable BD Leucocount™ Kit to be used with BD FACSuite™ Clinical application on BD FACSLyric™ Flow Cytometer.

BD FACSLyric™ Flow Cytometer – Summary of Device Comparison
Table 3 provides a comparison between the subject BD FACSLyric™ Flow Cytometer and its predicate device.

The only difference between the subject BD FACSLyric™ Flow Cytometer and its predicate is that the intended use statement will be updated to support use with the BD Leucocount™ Kit. All other aspects of the BD FACSLyric™ Flow Cytometer remain the same as described in the most recent BD FACSLyric™ Flow Cytometer 510(k) clearance K201814 (predicate).

Table 2. Comparison Between BD Leucocount™ Kit and its Predicate

Feature/Attribute	**Subject Device** **BD Leucocount™ Kit (with BD Leucocount™ Assay Module, for use with BD FACSLyric™ Flow Cytometer)**	**Predicate Device** **BD Leucocount™ Reagent Assay (BD Leucocount™ Kit) for use with BD FACSVia™ System** (BK150307)
Device Classification and Product Code	Regulation Description: Flow Cytometric Reagents and Accessories Regulatory Class: II Regulation Number: 21 CFR 864.5220 Product Code: OYE	
Intended Use / Indications for Use	The BD Leucocount™ Kit consists of BD Leucocount™ Reagent (propidium iodide fluorescent dye) and BD Trucount™ Tubes and is intended for use with the BD FACSCalibur™, BD FACSort™, BD FACScan™, BD FACSVia™, **and BD FACSLyric™ flow cytometer systems**, or for a flow cytometer equipped with a 488-nm laser able to threshold on propidium iodide fluorescence, for enumerating residual white blood cells (rWBCs) in leucoreduced blood products. For in vitro diagnostic use.	BD Leucocount™ Kit consists of BD Leucocount™ reagent (propidium iodide fluorescent dye) and BD Trucount™ tubes and is intended for use with the BD FACSCalibur™, BD FACSort™, BD FACScan™, and BD FACSVia™ flow cytometer systems, or for a flow cytometer equipped with a 488-nm argon ion laser able to threshold on FL2, for enumerating residual white blood cells (rWBCs) in leucoreduced blood products. For in vitro diagnostic use.
Reagents	BD Leucocount™ Kit • BD Leucocount™ Reagent • BD Trucount™ Tubes	

Feature/Attribute	Subject Device **BD Leucocount™ Kit (with BD Leucocount™ Assay Module, for use with BD FACSLyric™ Flow Cytometer)**	Predicate Device **BD Leucocount™ Reagent Assay (BD Leucocount™ Kit) for use with BD FACSVia™ System** (BK150307)
Detection/Assay Principle	The BD Leucocount™ Reagent contains propidium iodide fluorescent dye. Propidium iodide is a nucleic acid dye which, when used with RNAse, stains only cellular DNA. White blood cells are nucleated cells that contain DNA and are therefore stained with the dye. Non-nucleated particles (including platelets and red blood cells) do not stain with this reagent. BD Trucount™ Tubes contain beads that act as an internal reference to accurately determine the absolute count of residual white blood cells (rWBCs). Appropriate samples are combined with the lyophilized bead pellet in the BD Trucount™ Tube before staining. After staining rWBCs, samples are acquired on a flow cytometer. Absolute rWBC counts are determined by using a simple calculation based on bead number and sample volume.	
Specimen Type	Leucoreduced blood products, including: • Leucoreduced red blood cells • Leucoreduced platelets	
Sample Volume	100 µL	
Sample Preparation	Manual	
Instrument and Software Platform	**For BD FACSLyric™ Flow Cytometer:** • **BD FACSLyric™ Flow Cytometer using BD FACSuite™ Clinical application with BD Leucocount™ Assay Module** • **System adjusts/optimizes photomultiplier tube (PMT) voltages**	For BD FACSVia™ Flow Cytometer: • BD FACSVia™ Flow Cytometer using BD FACSVia™ Clinical software with BD Leucocount™ assay test definition file • Fixed PMT voltages
Software - Inputs	For BD FACSuite™ Clinical Application with BD Leucocount™ Assay Module: • Flow cytometry data. • Lot and expiry information for BD Trucount™ beads and setup beads. • **Lot and expiry information for reagents.** • Sample tube ID. • May also input the pack volume.	For BD FACSVia™ Clinical software with BD Leucocount™ assay test definition file: • Flow cytometry data. • Lot and expiry information for BD Trucount™ beads and setup beads. • Sample tube ID. • May also input the pack volume.

Feature/Attribute	Subject Device **BD Leucocount™ Kit (with BD Leucocount™ Assay Module, for use with BD FACSLyric™ Flow Cytometer)**	Predicate Device **BD Leucocount™ Reagent Assay (BD Leucocount™ Kit) for use with BD FACSVia™ System** (BK150307)
Software - Outputs	For BD FACSuite™ Clinical Application with BD Leucocount™ Assay Module: • BD Leucocount™ Lab Report • Assay Setup Report • Instrument QC Report	For BD FACSVia™ Clinical software with BD Leucocount™ assay test definition file: • BD Leucocount™ Lab Report • Instrument QC Report
Software – Operator/User	For BD FACSuite™ Clinical Application with BD Leucocount™ Assay Module: • Clinical laboratory personnel.	For BD FACSVia™ Clinical software with BD Leucocount™ assay test definition file: • Clinical laboratory personnel.
Software – Operator/User Actions	For BD FACSuite™ Clinical Application with BD Leucocount™ Assay Module: • Analysis gates/regions are automatically applied to the flow cytometry dot plots. The user inspects the dot plots, and the gates/regions may be adjusted by the user as needed. • Reports generated by the software with BD Leucocount™ Assay Module are reviewed by the user.	For BD FACSVia™ Clinical software with BD Leucocount™ assay test definition file: • Analysis gates/regions are automatically applied to the flow cytometry dot plots. The user inspects the dot plots, and the gates/regions may be adjusted by the user as needed. • Reports generated by the software with BD Leucocount™ assay test definition file are reviewed by the user.
Software – Acquisition Stopping Criteria	For BD FACSuite™ Clinical Application with BD Leucocount™ Assay Module: • 10,000 BD Trucount™ beads events collected. • Acquisition time limit: 5 minutes.	For BD FACSVia™ Clinical software with BD Leucocount™ assay test definition file: • 10,000 BD Trucount™ beads events collected. • Acquisition time limit: 5 minutes.
Software – Gated Analysis Events/ Populations	For BD FACSuite™ Clinical Application with BD Leucocount™ Assay Module: • Residual white blood cells (rWBCs) • BD Trucount™ Beads	For BD FACSVia™ Clinical software with BD Leucocount™ assay test definition file: • Residual white blood cells (rWBCs) • BD Trucount™ Beads

Feature/Attribute	Subject Device **BD Leucocount™ Kit (with BD Leucocount™ Assay Module, for use with BD FACSLyric™ Flow Cytometer)**	Predicate Device **BD Leucocount™ Reagent Assay (BD Leucocount™ Kit) for use with BD FACSVia™ System** (BK150307)
Software – rWBC Analysis Gate Type	<u>For BD FACSuite™ Clinical Application with BD Leucocount™ Assay Module:</u> • The rWBC population is identified by a default pre-defined gate template/region that is automatically set. The gate may be adjusted by the user as needed.	<u>For BD FACSVia™ Clinical software with BD Leucocount™ assay test definition file:</u> • The rWBC population is identified by a default pre-defined gate template/region that is automatically set. The gate may be adjusted by the user as needed.
Software – BD Trucount™ Beads Analysis Gate Type	<u>For BD FACSuite™ Clinical Application with BD Leucocount™ Assay Module:</u> • The BD Trucount™ Beads population is identified **with an algorithm gate** that is automatically set and adjusted**.** The gate may be adjusted further by the user as needed.	<u>For BD FACSVia™ Clinical software with BD Leucocount™ assay test definition file:</u> • The BD Trucount™ Beads population is identified by a default pre-defined gate template/region that is automatically set. The gate may be adjusted by the user as needed.
Instrument Configuration	**<u>For BD FACSLyric™ Flow Cytometer:</u>** • **Equipped to detect forward scatter, side scatter and up to six fluorescence channels for IVD use.** • **BD Leucocount™ reagent (propidium iodide) uses the blue laser's detector with the 586/42 filter.** • **BD Trucount™ absolute counting beads use the red laser's detector with the 660/10 filter.**	<u>For BD FACSVia™ Flow Cytometer:</u> • Equipped to detect forward scatter, side scatter and up to two fluorescence channels for IVD use. • BD Leucocount™ reagent (propidium iodide) uses the blue laser's detector with the 585/40 filter. • BD Trucount™ absolute counting beads use the blue laser's detector with the 533/30 filter.
Specimen Stability Age of Blood (AOB) Age of Stain (AOS)	Prepare and run the samples within 48 hours following leucoreduction. For specimens stained within 24 hours of leucoreduction, acquire the samples within 24 hours of staining. For specimens stained within 48 hours of leucoreduction, acquire the samples within 60 minutes of staining.	

Feature/Attribute	Subject Device **BD Leucocount™ Kit (with BD Leucocount™ Assay Module, for use with BD FACSLyric™ Flow Cytometer)**	Predicate Device **BD Leucocount™ Reagent Assay (BD Leucocount™ Kit) for use with BD FACSVia™ System** (BK150307)
Number of Tubes per Assay	1 Tube	
Measurement Range	For BD FACSLyric™ Flow Cytometer: 0.7 – 350 rWBCs/µL	For BD FACSVia™ Flow Cytometer: 0 – 350 rWBCs/µL
Results Reporting	Software-assisted report generation. The lab report provides the rWBC count in cells/µL. The lab report also provides the total rWBC count per pack, if the pack volume is entered.	

Table 3. Comparison Between BD FACSLyric™ Flow Cytometer and its Predicate

Feature/Attribute	Subject Device **BD FACSLyric™ Flow Cytometer**	Predicate Device **BD FACSLyric™ Flow Cytometer** (K201814)
Intended Use / Indications for Use	The BD FACSLyric™ flow cytometer is intended for use as an in vitro diagnostic device for the following: • Immunophenotyping using up to six fluorescence detection channels and two light scatter channels using a blue (488-nm) and a red (640-nm) laser. • **Enumeration of residual white blood cells (rWBCs) in leucoreduced blood products.** It is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.	The BD FACSLyric™ flow cytometer is intended for use as an in vitro diagnostic device for immunophenotyping using up to six fluorescence detection channels and two light scatter channels using a blue (488-nm) and a red (640-nm) laser. It is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.

7. Performance Data

The following performance studies were conducted to support the substantial equivalency determination.

Table 4. BD Leucocount™ Kit Bench Performance Studies

Study	Standard	Objective	Results
Within-Site Precision Using Control Materials	CLSI EP05-A3	To evaluate the precision performance of BD Leucocount™ Kit on the BD FACSLyric™ Flow Cytometer.	All acceptance criteria were met.
Repeatability Evaluation Using Clinical Specimens	CLSI EP05-A3	To verify repeatability performance of BD Leucocount™ Kit on the BD FACSLyric™ Flow Cytometer through testing clinical specimens.	All acceptance criteria were met.
Linearity	CLSI EP06-Ed2	To evaluate the linear range of the BD Leucocount™ Kit using BD FACSLyric™ Flow Cytometer, for measuring residual White Blood Cell (rWBC) absolute counts.	The linear range for rWBC absolute counts using BD Leucocount™ Kit on BD FACSLyric™ Flow Cytometer was established based on the acceptance criteria.
Limit of Blank	CLSI EP17-A2	To evaluate Limit of Blank of BD Leucocount™ Kit with BD FACSLyric™ Flow Cytometer.	The Limit of Blank (LoB) is 0 cells/µL for rWBC absolute counts.
Limit of Quantitation	CLSI EP17-A2	To evaluate Limit of Quantitation of BD Leucocount™ Kit with BD FACSLyric™ Flow Cytometer.	The Limit of Quantitation (LoQ) is 0.7 cells/µL for rWBC absolute counts.
Interfering Substances	CLSI EP07-Ed3 CLSI EP37-Ed1	To assess the performance of BD Leucocount™ Kit for use with BD FACSLyric™ Flow Cytometer in the presence of potential endogenous and exogenous interfering substances.	There was no detectable interference for all the tested substances, with the exception of triglycerides, a known interferent that causes light scattering changes. This interfering condition caused by lipemic specimens will be reflected in the instructions for use.
Sample and Reagent Carryover	CLSI H26-A2	To evaluate sample and reagent carryover using BD Leucocount™ Kit with BD FACSLyric™ Flow Cytometer.	All acceptance criteria were met.

Study	Standard	Objective	Results
BD FACSLyric™ Manual Versus Loader Acquisition Equivalency	CLSI EP09c	To determine the method bias of the BD Leucocount™ Kit for samples acquired on the BD FACSLyric™ Flow Cytometer using BD FACS™ Universal Loader, versus samples that are acquired manually.	All acceptance criteria were met.
Anticoagulants	CLSI EP07-Ed3	To assess the compatibility of the BD Leucocount™ Kit with various anticoagulants used in blood products collection and storage.	All tested anticoagulants (ACD, CPD, CP2D, CPDA, EDTA, 4% Sodium Citrate, Heparin) met the study acceptance criteria.

Table 5. BD Leucocount™ Kit Performance Studies Conducted at Clinical Sites

Study	Standard	Objective	Results
Method Comparison	CLSI EP09c	To determine the method bias between the subject device (BD Leucocount™ Kit on BD FACSLyric™ Flow Cytometer) versus the predicate device (BD Leucocount™ Kit on BD FACSVia™ Flow Cytometer).	A total of 520 specimens were enrolled across four testing sites. 502 specimens were evaluable. 18 specimens were non-evaluable. The acceptance criteria were met.
Inter-Site Reproducibility	CLSI EP05-A3	To assess inter-site reproducibility of BD Leucocount™ Kit on BD FACSLyric™ Flow Cytometer.	The results of inter-site reproducibility for the BD Leucocount™ Kit on the BD FACSLyric™ Flow Cytometer demonstrated that the variability across three sites met study acceptance criteria.
Specimen Stability	CLSI EP25-A	To support the sample stability and stained sample stability claims for leucoreduced red blood cells and leucoreduced platelets.	The acceptance criteria were met. The results from the study support the specimen stability claims.

8. Conclusion

The subject device, BD Leucocount™ Kit (with BD Leucocount™ Assay Module, to enable use with the BD FACSLyric™ Flow Cytometer), is substantially equivalent to the predicate device, BD Leucocount™ Kit (for use with the BD FACSVia™ Flow Cytometer).