510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K201814

B Applicant

Becton, Dickinson and Company

C Proprietary and Established Names

BD FACSLyric Flow Cytometer
BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
OYE	Class II	21 CFR 864.5220 - Automated Differential Cell Counter	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Modification of previously cleared instrument

B Type of Test:

Quantitative and Semi-Quantitative Flow Cytometric Immunoassays

III Intended Use/Indications for Use:

A Intended Use(s):

BD FACSLyric Flow Cytometer

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.

BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System

The BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System 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 includes an automated sample preparation system used to prepare human peripheral whole blood samples for acquisition and analysis and is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.

B Indication(s) for Use:

Same as above.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

Refer to K170974 for detailed description and functioning of the BD FACSLyric flow cytometer.

The modified BD FACSLyric Flow Cytometer consists of the following components.

- FACSLyric Flow Cytometer (3-1, 4-2, 4-2-2 ,4-3-3 and 4-3-5 optical configurations)
- FACSuite Clinical Software (version 1.4)
- Modified FACS Universal Loader: updated shaker and modification to the door lock and sensor connections
- Modified CMS firmware

BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation system consists of all the above components as FACSLyric Flow Cytometer and additionally contain:

- BD FACSDuet Sample Preparation system physically and data integrated with the BD FACSLyric Flow Cytometer
- FACSDuet fluidics that contain saline, deionized (DI) water and 10% bleach solution.
- Modified FACS Universal Loader: updated shaker, modification to the door lock and sensor connections, addition of stabilization bracket

B Instrument Description Information:

1. Instrument Name:

   BD FACSLyric Flow Cytometer
   BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation system

2. Specimen Identification:

   BD FACSLyric Flow Cytometer: Manual Entry

   BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation system: Barcode Reader

3. Specimen Sampling and Handling:

   BD FACSLyric Flow Cytometer: Specimens will be manually prepared by the operator/user.

   BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation system: Specimens will be automatically prepared by FACSDuet sample preparation system.

4. Calibration:

   Calibration is performed with the IVD assay intended for use with the instruments.

5. Quality Control:

   Quality control is performed with the IVD assay intended for use with the instruments.

V Substantial Equivalence Information:

A Predicate Device Name(s):

BD FACSLyric Flow Cytometer (3-1, 4-2, 4-2-2 and 4-3-3 optical configurations), BD FACSuite Clinical Software, BD Multitest 6-Color Assays, BD Multitest 4-Color Assays, BD Multitest 6-Color TBNK

B Predicate 510(k) Number(s):

K170974

C Comparison with Predicate(s):

Device & Predicate Device(s):	**K170974 (Predicate)**	**K201814**	
Device Trade Name	BD FACSLyric Flow Cytometer (3-1, 4-2, 4-2-2 and 4-3-3 Configurations)	BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System (3-1, 4-2, 4-2-2, 4-3-3, 4-3-5 Configurations)	BD FACSLyric Flow Cytometer (3-1, 4-2, 4-2-2, 4-3-3, 4-3-5 Configurations)

General Device Characteristic Similarities			
Device Classification and Product Code	• Automated differential cell counter • Regulatory Class: II • Regulation Number: 21 CFR 864.5220 • Product Code: OYE	Same	Same
Assay Methodology	Flow Cytometry	Same	Same
Detection/Assay Principle	Immunofluorescence	Same	Same
Specimen Type	Peripheral whole blood	Same	Same
Sample Volume	50 µL	Same	Same
Maximum Parameter Detectors	IVD detection channels Six Fluorescence channels plus forward scatter and side scatter	Same	Same
IVD Lasers/Excitation	Blue Laser: Wavelength: 488 nm Optical power: 20 mW Red Laser: Wavelength: 640 nm Optical power: 40 mW	Same	Same
Electronics	Up to 35000 events/sec	Same	Same
Forward Scatter Detection	Photodiode with built in 488/10 bandpass filter	Same	Same
Fluorescence and Side Scatter Detection	• Reflective optics with single transmission bandpass filter in front of each PMT • High performance PMT modules for all fluorescence and side scatter channels • Light collected by objective lens is delivered by fiber optics especially designed detector arrays	Same	Same

	• The cuvette flow cell is gel-coupled by refractive index-matching optical gel to the fluorescence objective lens (1.2 NA) for optimal collection efficiency		
Results Reporting	Software-assisted report generation	Same	Same
General Device Characteristic Differences			
Intended Use / Indications For Use	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.	The BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System 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 includes an automated sample preparation system used to prepare human peripheral whole blood samples for acquisition and analysis and is intended for use with in vitro diagnostic (IVD) assays and software that are indicated for use with the instrument.	Same as predicate
Optical Configurations	• 2-laser (blue, red), 4-color (3-1) • 2-laser (blue, red), 6-color (4-2) • 3-laser (blue, red, violet), 8-color (4-2-2)	• 2-laser (blue, red), 4-color (3-1) • 2-laser (blue, red), 6-color (4-2) • 3-laser (blue, red, violet), 8-color (4-2-2)	• 2-laser (blue, red), 4-color (3-1) • 2-laser (blue, red), 6-color (4-2) • 3-laser (blue, red, violet), 8-color (4-2-2)

	• 3-laser (blue, red, violet), 10-color (4-3-3)	• 3-laser (blue, red, violet), 10-color (4-3-3) • 3 laser (blue, red, violet), 12-color (4-3-5) configuration	• 3-laser (blue, red, violet), 10-color (4-3-3) • 3 laser (blue, red, violet), 12-color (4-3-5) configuration
Fluidics	FACSLyric Flow Cytometer fluidics - • Uses FACSFlow as the sheath fluid • Uses 10% bleach solution for system cleaning	FACSDuet fluidics- • Uses DI water for washing the reagent and specimen probes • Uses 10% bleach solution for cleaning the specimen probe during the FACSDuet End of Day Clean task. • Uses saline for washing the specimen probe	Same as predicate
Software	FACSuite Clinical software (version 1.0)	• Modified FACSuite Clinical software (version 1.4) • FACSDuet software	Modified FACSuite Clinical software (version 1.4)
Firmware	CMS firmware	• Modified CMS Firmware • FACSDuet firmware	Modified CMS Firmware
Loader	FACS Universal Loader	Modified FACS Universal Loader with following changes: • Updated shaker to have a more robust mechanism for the gripper fingers which hold on to the sample carrier; • Modification to the door lock and sensor connections to enable automated transfer of sample carriers from FACSDuet to FACSLyric; • Replacement of the loader outside cover (skins) and window, including relocation of loader label and	Modified FACS Universal Loader with the following changes: • Updated shaker to have a more robust mechanism for the gripper fingers which hold on to the sample carrier; • Modification to the door lock and sensor connections to enable automated transfer of sample carriers from FACSDuet to FACSLyric

		status light (for physical integration only); • Addition of a stabilization bracket connecting FACS Universal Loader to FACSDuet instrument (for physical integration only.)	
Sample Introduction	• Manual loading onto the tube port of the flow cytometer • Automated loading through a multi-tube FACS Universal Loader	FACSDuet instrument will automatically transfer the 30 or 40-tube sample carrier to the modified FACS Universal Loader	Same as predicate
Sample Preparation	Manual	Automated with FACSDuet Sample Preparation System	Manual
Pipetting	Reverse pipetting for peripheral blood	Automated Sample Preparation	Same as predicate
Specimen Tube Mixing	Mixing manually	Automated Sample Preparation	Same as predicate
Incubation Time	15 minutes	15–30 minutes	15 minutes
Dimensions (W x D x H)	63.3 x 57.9 x 57.9 cm (24.93 x 22.8 x 22.8 in)	282.9 x 77.1 x 85.0 cm (111.4 x 30.4 x 33.5 in)	Same as predicate
Quality Control & Instrument Setup	• Daily QC performed using CS&T beads • QC is also preformed every 6 months using CS&T beads. It includes all of the measurements performed in daily QC along with additional more detailed measurements and an automatic laser alignment. • Daily instrument setup using CS&T beads	• FACSLyric flow cytometer: Same • FACSDuet instrument: - Initialization - Verification of dispense accuracy and precision - Process controls: Multi-Check Control and Multi-Check CD4 Low Control	Same as predicate

	• FC Beads are run every 2 months to measure and reset instrument spectral overlap values as part of the instrument setup.		

VI Standards/Guidance Documents Referenced:

The following FDA Guidances were followed in the assessment of this device's modifications and in the preparation of this submission:

Organization	Standard and Version	Title
CLSI	EP05-A3	Evaluation of Precision Performance of Quantitative Measurement Methods
CLSI	EP6-A	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach
CLSI	EP17-A2	Protocols for Determination of Limits of Detection and Limits of Quantification
CLSI	EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents
CLSI	H26-A2	Validation, Verification, and Quality Assurance of Automated Hematology Analyzers
CLSI	EP09c	Measurement Procedure Comparison and Bias Estimation Using Patient Samples
IEC	61010-1	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements
IEC	61010-2-101	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment.
EN-ISO	14971:2012	Application of Risk Management to Medical Devices
ISO	14971:2007	Application of Risk Management to Medical Devices

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The performance of the modified instruments was evaluated by using BD Multitest 6-colcor TBNK with Trucount Tubes (K060375) as a representative reagent. As the BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System represents the more complex configuration and uses the same flow cytometer with some minor differences in sample loader comparing to the modified BD FACSLyric Flow Cytometer without FACSDuet, the analytical performance was validated only on the integrated system.

All results below met the manufacturer's pre-specified acceptance criteria.

1. Precision/Reproducibility:

The precision and reproducibility studies were performed based on CLSI guidance document EP05-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition.*

The precision study was performed by testing Streck CD Chex plus Normal (CDN) and Streck CD Chex CD4 Low (CDL) as stable samples. Daily measurements were obtained in two separate runs (separated by at least two hours from the start of the first run's acquisition to the start of second run's acquisition) over 21 testing days. System precision performance for the enumeration of the T-, B- and NK- lymphocyte subset percentages and absolute counts was evaluated across three FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation systems, executed by three operators using three reagent lots for each assay through the study. The precision based on the results of absolute counts and percentage lymphocytes are summarized in the following tables:

Precision of Absolute Count Test Results for Each Subset

Control Level	Subset	Mean (cells/µL)	Within-Run % CV	Total % CV
CDL	CD3+	746.17	3.85	5.30
	CD3+CD4+	174.87	6.39	6.57
	CD3+CD8+	514.67	5.17	5.33
	CD19+	213.05	5.52	6.39
	CD16+CD56+	194.76	5.82	6.98
CDN	CD3+	1762.40	5.74	7.98
	CD3+CD4+	1109.82	6.97	7.52
	CD3+CD8+	630.75	7.77	8.43
	CD19+	268.73	7.34	9.51
	CD16+CD56+	223.94	7.98	10.28

Precision of Percentage of Lymphocyte (%) Test Results for Each Subset

Control Level	Subset	Mean (% Lymphocyte)	Within-Run % CV	Total % CV
CDL	% CD3+	64.11	1.49	1.49
	% CD3+CD4+	15.02	4.66	4.72
	% CD3+CD8+	44.16	2.42	2.49
	% CD19+	18.31	4.04	4.04
	%CD16+CD56+	16.73	4.60	4.60
CDN	% CD3+	77.76	1.09	1.09
	% CD3+CD4+	48.97	1.93	1.96
	% CD3+CD8+	27.77	2.95	3.42
	% CD19+	11.86	5.31	5.39
	%CD16+CD56+	9.88	5.97	5.97

The whole blood repeatability was evaluated using 27 samples comprised of patient and normal whole blood specimens with at least 50% of specimens from HIV patients. System repeatability was determined by enumeration of CD3+, CD3+CD4+, CD3+CD8+, CD19+ and CD16+56+ lymphocyte subset percentages and absolute counts across three FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation systems with three reagent lots. Each specimen was tested with two replicates/reagent lot/instrument. The precision based on the results of absolute counts and percentage lymphocytes are summarized in the following tables:

Precision (Whole Blood) of Absolute Count Test Results for Each Subset

Subset	Mean (cells/µL)	Within-Run % CV	Total % CV
CD3+	1610.26	4.17	4.32
CD3+CD4+	174.87	4.92	5.03
CD3+CD8+	657.09	5.17	5.35
CD19+	213.05	7.47	7.47
CD16+CD56+	927.05	10.13	10.41

Percentage (Whole Blood) of Lymphocyte (%) Test Results for Each Subset

Subset	Mean (% Lymphocyte)	Within-Run % CV	Total % CV
CD3+	76.74	0.97	0.97
CD3+CD4+	31.34	0.93	0.93
CD3+CD8+	43.94	1.03	1.04
CD19+	12.07	0.72	0.72
CD16+CD56+	10.71	0.85	0.86

Inter-laboratory reproducibility was performed by testing two levels of Streck CD-check plus (CDN) and CD-chex plus CD4 low (CDL) samples at three different clinical sites for a total of 15 days (two runs/day) using three reagent lots. The test was done with a minimum of one operator per instrument per site. The reproducibility based on the results of absolute counts are summarized in the following table:

Control Level	Subset	Mean (cells/µL)	Within-Run % CV	Between-Run % CV	Between-Day % CV	Between-Site % CV	Total % CV
CDL	CD3+	944.80	5.98	0.00	1.65	4.01	7.59
	CD3+CD4+	162.68	8.74	0.00	1.30	4.30	9.97
	CD3+CD8+	705.39	6.29	0.00	1.66	3.76	7.69
	CD19+	352.33	6.55	0.00	1.58	3.85	7.93
	CD16+CD56+	331.07	7.38	0.00	1.22	4.17	8.72
CDN	CD3+	1959.56	5.33	0.00	1.06	3.52	6.64
	CD3+CD4+	1281.09	5.52	0.00	1.02	3.56	6.81
	CD3+CD8+	654.89	6.38	0.00	1.56	2.25	7.00
	CD19+	314.41	7.35	0.00	0.78	3.49	8.27
	CD16+CD56+	286.50	8.10	1.91	0.36	3.86	9.32

2. Linearity:

The linearity of the assay run on the BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System was performed based on CLSI EP6-A, *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.*

Triplicate measurements of 11 lymphocyte subsets covering the anticipated linear ranges were tested using three reagent lots on three different BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation Systems. In addition, seven supplemental concentration levels for CD4 were used to evaluate linearity over the medical decision point at 50 and 250 cells/µL for CD4 absolute counts. The results of the absolute counts in supporting the linear range for each subset are summarized in the following table:

Subset	Linear Range (cells/µL)
CD3+	5 – 5282
CD3+CD4+	3 – 3188
CD3+CD8+	2 – 3268
CD19+	0 – 2295
CD16+CD56+	1 – 1287

3. Analytical Specificity/Interference:

Not applicable

4. Accuracy (Instrument):

The study was performed in accordance with CLSI EP09c, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples* by testing 370 samples at three different clinical sites (minimum 40 samples/site) to demonstrate the equivalence of the BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System to the FACSLyric Flow Cytometer using manual sample preparation (predicate). CD4+ bins were designed to cover the analytical measuring range (AMR). Each sample was stained with BD Multicolor 6-color TBNK reagents and run on one new instrument system and one predicate instrument at each site. Deming regression analysis was performed with all data combined for each subset, and the results of the absolute counts and percentage lymphocytes are summarized in the following tables:

Regression Analysis Using Absolute Count Test Results for Each Subset

Subset	Range (cells/µL)	Slope (95% CI)	Intercept
Abs CD3+	89–10753	1.00 (0.99, 1.01)	-3.96
Abs CD3+CD4+	3–7201	1.00 (0.99, 1.00)	-1.19
Abs CD3+CD8+	50–5083	1.00 (0.99, 1.02)	-5.19
Abs CD19+	8–1919	0.99 (0.97, 1.00)	-0.45
Abs CD16+CD56+	9–2171	1.01 (0.98, 1.03)	2.18

Regression Analysis Using Percentage of Lymphocyte (%) Test Results for Each Subset

Subset	Range (% of Lymphocyte)	Slope (95% CI)	Intercept
% CD3+	45.26–99.14	1.00 (0.99, 1.02)	-0.31
% CD3+CD4+	0.27–85.83	0.99 (0.98, 1.00)	0.15
% CD3+CD8+	1.54–86.88	1.01 (0.99, 1.01)	0.17
% CD19+	0.13–33.03	0.99 (0.98, 1.01)	-0.04
% CD16+CD56+	0.5–47.54	1.01 (0.99, 1.03)	0.11

5. Carry-Over:

The carryover studies were performed based on CLSI H26-A2, *Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard- Second Edition*.

Specimen Carryover
Specimen carry over studies were performed to determine whether results were affected by contamination from neighboring samples. System carryover was evaluated by estimating the percent carryover of abnormally high leukocyte count samples to abnormally low leukocyte count samples. Fifty-four (54) samples were acquired for high and 54 samples were acquired for the low leukocyte concentrations across three FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation Systems from a total of six donors. Specimen to specimen carryover results across all three instruments and donors was < 0.2% (i.e., 2000 ppm v/v).

Bleach to specimen carryover was evaluated on three different BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation Systems by performing the end of the day clean maintenance task using bleach and the pipetting deionized water in each specimen tube. This was repeated 12 times with 12 different specimen tubes which were combined into one tube to measure the residual bleach. Bleach to specimen carryover over all three instruments was < 0.00002% (i.e., 0.2 ppm v/v).

Reagent Carryover
The reagent carryover within the BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation Systems was evaluated by measuring optical density of FITC and PBS reagents using a spectrophotometer, before and after 100 cycles of reagent probe dispenses and washes, to assess the adequacy of probe washes to prevent contamination. The reagent carryover was found to be < 0.01% (i.e., 100 ppm v/v).

B Other Supportive Instrument Performance Characteristics Data:

1. Detection Limit:

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) were determined per CLSI EP17-A2, *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline*.

For LoB, five donor samples with a minimum of 60 replicates per reagent lot, were evaluated across four days using three different BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation Systems. There were 194 data points collected in total for three reagent lots.

For LoD, four low concentration samples with a minimum of 60 replicates per reagent lot were evaluated across four days using three different BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation Systems for low concentration samples per reagent lot. The samples were cell-free plasma reconstituted with normal donor whole blood to a concentration of 10 $\pm$ 5 CD4 cells/uL. A total of 180 points were collected in total for three reagent lots.

For LoQ, four low concentration pools were created by diluting normal whole blood with cell free plasma to achieve CD4 absolute counts of 10, 20, 30 and 50 cells/µL. Fifteen replicates were prepared from each of the concentration pools and were stained with three different reagent lots. Ten replicates from each of the concentration pools were run on three different BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation System whereas five replicates were run on the BD FACSLyric Flow cytomter (predicate device).

The determined LoB, LoD and LoQ are shown in the following table:

Subset	LoB (cells/µL)	LoD (cells/µL)	LoQ (cells/µL)
CD3+	2	6	18
CD3+CD4+	1	4	9
CD3+CD8+	2	8	13
CD19+	0	2	7
CD16+CD56+	0	3	12

2. In-use Reagent Stability Performance:

The study was performed in accordance with *CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents* to evaluate the in-use reagent stability of the Multitest 6-color TBNK on the FACSDuet instrument for a minimum of 5 days with the vials remaining uncapped for 8 hours per day inside the FACSDuet instrument. The enumeration of CD3+, CD3+CD4+, CD3+CD8+, CD19+ and CD16+CD56+ was tested over three different BD FACSLyric Flow Cytometer with the integrated BD FACSDuet Sample Preparation Systems using three reagent lots. The unopened vials stored refrigerated (2–8 ºC) from the same lots were used as control reagents. Samples that were stained with control reagents were either prepared by Automated sample preparation and acquired on the subject device or by manual preparation and acquired on unintegrated FACSLyric flow cytometer (predicate device). The results for the absolute counts and percentage lymphocytes between the test (Day 5) and the control reagents for the automatic sample preparation and manual sample preparation method are summarized in the following table:

Subset	Absolute Count (cells/µL) (Mean % Bias)		Percent Lymphocyte (%) (Mean % Bias)	
	Automatic	Manual	Automatic	Manual
CD3+	-2.51	-0.12	0.08	0.02
CD3+CD4+	-2.48	-0.07	0.14	0.21
CD3+CD8+	-2.30	-0.34	0.04	-0.10
CD19+	-2.50	-0.14	-0.11	-0.12
CD16+CD56+	-2.06	3.57	0.03	0.11

3. Equivalence between 15- and 30-minutes Incubation time:

   The study was performed to demonstrate the equivalency between the sample staining incubation time of 15 minutes for the manual preparation versus the staining incubation time of 15–30 minutes on the FACSDuet instrument for the following four comparisons:

   a. Between FACSDuet 30 minutes incubation time and manual sample preparation 15 minutes incubation time.
   b. Between 15 and 30 minutes incubation time using manual sample preparation.
   c. Between FACSDuet and manual sample preparation using incubation time of 15 minutes.
   d. Between FACSDuet and manual sample preparation using incubation time of 30 minutes.

   For each of the four sample preparation types, 12 donor samples with 5 replicates per donor (60 replicates in total) were tested for enumeration of the CD3+, CD3+CD4+, CD3+CD8+, CD19+ and CD16+CD56+ cells. Mean bias (%) of absolute counts for all four comparisons were calculated and the results support the equivalence between 15 and 30 minutes incubation time.

4. Equivalency of Software for the BD FACSLyric Flow Cytometer:

   There were three software versions (v1.1.1, v1.3 and v1.4) releases from the predicate (v 1.0, predicate) to the current modified BD FACSLyric Flow Cytometer (v 1.4). Equivalency of software versions between the predicate system and the subject device was performed as follows:

   Equivalency between software v1.1.1 and v1.3

   A study was performed to evaluate the optical equivalence between the predicate instrument (the BD FACSLyric 10-color configuration with software v1.1.1) and subject device (the BD FACSLyric 12-color configuration with software v1.3.). The clinical samples containing both HIV positive patient samples and normal samples were tested for absolute enumeration of the lymphocyte subsets on three subject instruments and three predicate instruments using three reagent lots. The results for the absolute counts and percentage lymphocytes are summarized in the following table:

Subset	Absolute Count (cells/µL) (Mean % Bias)	Percent Lymphocyte (%) (Mean % Bias)
CD3+	-0.17	-0.21
CD3+CD4+	-0.52	-0.54
CD3+CD8+	-0.83	-0.86
CD19+	0.27	0.03
CD16+CD56+	1.29	0.15

Equivalency between software v1.3 and v1.4

Twenty clinical samples containing both HIV positive samples and normal samples were evaluated for absolute count measurement to determine equivalency between FACSLyric containing v1.3 and FACSLyric containing v1.4. The results for the absolute counts and percentage lymphocytes are summarized in the following table:

Subset	Absolute Count (cells/µL) (Mean % Bias)	Percent Lymphocyte (%) (Mean % Bias)
CD3+	-1.50	0.21
CD3+CD4+	-0.94	0.55
CD3+CD8+	-1.49	0.25
CD19+	-0.10	-0.09
CD16+CD56+	-0.58	0.03

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.