DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 28, 2017

Becton, Dickinson and Company
Li Zhou
Manager, Regulatory Affairs, BD Biosciences
2350 Qume Drive
San Jose, CA 95131

Re: K170974
Trade/Device Name: BD FACSLyric™ Flow Cytometer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: OYE
Dated: March 31, 2017
Received: April 03, 2017

Dear Ms. Zhou:

This letter corrects our substantially equivalent letter of July 3, 2017.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170974

Device Name

BD FACSLyric™ Flow Cytometer

Indications for Use *(Describe)*

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 Multitest™ 6-color TBNK, BD Multitest™ IMK kit, BD Multitest™ CD3/CD8/CD45/CD4, and BD Multitest™ CD3/CD16+CD56/CD45/CD19, all with optional BD Trucount™ tubes, are intended for use on the BD FACSLyric flow cytometer with peripheral whole blood for immunophenotyping. These reagents are indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency. These reagents determine the percentages and absolute counts of the following mature human lymphocyte subsets:

BD Multitest 6-color TBNK with optional BD Trucount tubes
- T lymphocytes (CD3+)
- B lymphocytes (CD19+)
- Natural killer (NK) lymphocytes (CD3–CD16+ and/or CD56+)
- Helper/inducer T lymphocytes (CD3+CD4+)
- Suppressor/cytotoxic T lymphocytes (CD3+CD8+)

BD Multitest IMK kit with optional BD Trucount tubes
- T lymphocytes (CD3+)
- B lymphocytes (CD19+)
- Natural killer (NK) lymphocytes (CD3–CD16+ and/or CD56+)
- Helper/inducer T lymphocytes (CD3+CD4+)
- Suppressor/cytotoxic T lymphocytes (CD3+CD8+)

BD Multitest CD3/CD8/CD45/CD4 with optional BD Trucount tubes
- T lymphocytes (CD3+)
- Suppressor/cytotoxic T lymphocytes (CD3+CD8+)
- Helper/inducer T lymphocytes (CD3+CD4+)

BD Multitest CD3/CD16+CD56/CD45/CD19 with optional BD Trucount tubes
- T lymphocytes (CD3+)
- Natural killer (NK) lymphocytes (CD3–CD16+ and/or CD56+)
- B lymphocytes (CD3–CD19+)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 510(k) Summary

This bundled 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: March 31, 2017

5.1 Submitted By

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

Contact: Li Zhou
Manager, Regulatory Affairs
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5.2 Device

Trade Name/Device Name: 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

5.3 Predicate Device

The predicate device is BD FACSCanto™ II system with BD Multitest™ reagents that consists of the following:

- FACSCanto II flow cytometer (4-2, 4-2-2 and 5-3 optical configurations) (K141468 and K062087)
- FACSCanto Clinical Software (Multitest 6-Color and 4-Color assays are included as panels within FACSCanto Clinical software) (K141468 and K062087)
- FACS 7-Color Setup Beads (K040026)
- Multitest 6-Color TBNK (K090967)
- Multitest IMK Kit (K980858)
- Multitest CD3/CD8/CD45/CD4 (K974360)
- Multitest CD3/C16+CD56/CD45/CD19 (K980858)
- Multi-Check Control (K961610)
- Multi-Check CD4 Low Control (K982231)
- Trucount Tubes (K970836)
- Optional FACS Loader (K141468 and K062087)

5.4 Device Description

The BD FACSLyric Flow Cytometer consists of the following components.

- FACSLyric Flow Cytometer (3-1, 4-2, 4-2-2 and 4-3-3 optical configurations)
- FACSuite Clinical Software
- Multitest 6-Color Assay Modules
- Multitest 4-Color Assay Modules
- FC Beads 7-Color Kit
- CS&T Beads
- Multitest 6-Color TBNK
- Multitest IMK Kit
- Multitest CD3/CD8/CD45/CD4
- Multitest CD3/CD16+CD56/CD45/CD19
- Multi-Check Control
- Multi-Check CD4 Low Control
- Trucount Tubes
- Optional FACS Universal Loader

In accordance with FDA Guidance for Industry and FDA Staff, *Bundling Multiple Devices or Multiple Indications in a Single Submission*, dated June 22, 2007, four Multitest assays with the instrument, beads and process controls are bundled within this submission.

The FACSLyric System with Multitest Reagents is intended for the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency using flow cytometry applications.

The system is an immunofluorescence assay system for identification and enumeration of lymphocyte subsets in peripheral whole blood. When blood is added to the monoclonal antibody reagent, the fluorochrome-labeled antibodies in the reagent bind specifically to lymphocyte surface antigens. During acquisition, the cells travel past one or more laser beams in a single file and scatter the laser light. The stained cells fluoresce. The scatter and fluorescence light is detected by the flow cytometer, separated by dichroic mirrors and optical filters, and then quantified with photomultiplier tubes (PMTs) to determine the percent lymphocyte of particular cell populations.

Multiple monoclonal antibodies each labeled with a different fluorochrome are contained within one reagent tube to simultaneously identify multiple lymphocyte subset populations. The use of Trucount tubes provides the absolute number of the fluorochrome-labeled antibody bound cells.

The FACSLyric System with Multitest Reagents is intended for Prescription Use Only and will be labeled “Rx Only”.

5.5 Indications for Use

5.6.1 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 Multitest™ 6-color TBNK, BD Multitest™ IMK kit, BD Multitest™ CD3/CD8/CD45/CD4, and BD Multitest™ CD3/CD16+CD56/CD45/CD19, all with optional BD Trucount™ tubes, are intended for use on the BD FACSLyric flow cytometer with peripheral whole blood for immunophenotyping. These reagents are indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency. These reagents determine the percentages and absolute counts of the following mature human lymphocyte subsets:

BD Multitest 6-color TBNK with optional BD Trucount tubes

- T lymphocytes ($CD3^+$)
- B lymphocytes ($CD19^+$)
- Natural killer (NK) lymphocytes ($CD3^-CD16^+$ and/or $CD56^+$)
- Helper/inducer T lymphocytes ($CD3^+CD4^+$)
- Suppressor/cytotoxic T lymphocytes ($CD3^+CD8^+$)

BD Multitest IMK kit with optional BD Trucount tubes

- T lymphocytes ($CD3^+$)
- B lymphocytes ($CD19^+$)
- Natural killer (NK) lymphocytes ($CD3^-CD16^+$ and/or $CD56^+$)
- Helper/inducer T lymphocytes ($CD3^+CD4^+$)
- Suppressor/cytotoxic T lymphocytes ($CD3^+CD8^+$)

BD Multitest CD3/CD8/CD45/CD4 with optional BD Trucount tubes

- T lymphocytes (CD3+)
- Suppressor/cytotoxic T lymphocytes (CD3+CD8+)
- Helper/inducer T lymphocytes (CD3+CD4+)

BD Multitest CD3/CD16+CD56/CD45/CD19 with optional BD Trucount tubes

- T lymphocytes (CD3+)
- Natural killer (NK) lymphocytes (CD3–CD16+ and/or CD56+)
- B lymphocytes (CD3–CD19+)

5.6.2 BD FC beads 7-color kit

The BD™ FC beads 7-color kit (BD FC beads), in conjunction with BD FACSuite™ Clinical software and BD™ CS&T beads, are used to establish fluorescence compensation for the BD FACSLyric™ flow cytometer.

5.6.3 BD CS&T beads

BD™ CS&T beads, in conjunction with BD FACSuite™ Clinical software, provide a standardized method for the quality control of optics, electronics, and fluidics, and for adjusting detector voltages and fluorescence compensation on the BD FACSLyric™ flow cytometer.

5.6.4 BD Multitest 6-color TBNK

BD Multitest™ 6-color TBNK with optional BD Trucount™ tubes is intended for use with BD FACSLyric™, BD FACSCanto™ II, and BD FACSCanto™ flow cytometers to determine the percentages and absolute counts of the following mature human lymphocyte subsets in peripheral whole blood for immunophenotyping:

- T lymphocytes ($CD3^+$)
- B lymphocytes ($CD19^+$)
- Natural killer (NK) lymphocytes ($CD3^-CD16^+$ and/or $CD56^+$)
- Helper/inducer T lymphocytes ($CD3^+CD4^+$)
- Suppressor/cytotoxic T lymphocytes ($CD3^+CD8^+$)

This reagent is indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency.

5.6.5 BD Multitest IMK Kit

BD Multitest™ IMK kit with optional BD Trucount™ tubes is intended for use with BD FACSLyric™, BD FACSCanto™ II, BD FACSCanto™ , and BD FACSCalibur™ flow cytometers to determine the percentages and absolute counts of the following mature human lymphocyte subsets in peripheral whole blood for immunophenotyping:

- T lymphocytes (CD3+)
- B lymphocytes (CD19+)
- Natural killer (NK) lymphocytes (CD3–CD16+ and/or CD56+)
- Helper/inducer T lymphocytes (CD3+CD4+)
- Suppressor/cytotoxic T lymphocytes (CD3+CD8+)

This reagent is indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency.

5.6.6 BD Multitest CD3/CD8/CD45/CD4

BD Multitest™ CD3/CD8/CD45/CD4 with optional BD Trucount™ tubes is intended for use with BD FACSLyric™, BD FACSCanto™ II, BD FACSCanto™, and BD FACSCalibur™ flow cytometers to determine the percentages and absolute counts of the following mature human lymphocyte subsets in peripheral whole blood for immunophenotyping:

- T lymphocytes (CD3+)
- Helper/inducer T lymphocytes (CD3+CD4+)
- Suppressor/cytotoxic T lymphocytes (CD3+CD8+)

This reagent is indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency.

5.6.7 BD Multitest CD3/CD16+CD56/CD45/CD19

BD Multitest™ CD3/CD16+CD56/CD45/CD19 with optional BD Trucount™ tubes is intended for use with BD FACSLyric™, BD FACSCanto™ II, BD FACSCanto™, and BD FACSCalibur™ flow cytometers to determine the percentages and absolute counts of the following mature human lymphocyte subsets in peripheral whole blood for immunophenotyping:

- T lymphocytes (CD3+)
- Natural killer (NK) lymphocytes (CD3–CD16+ and/or CD56+)
- B lymphocytes (CD3–CD19+)

This reagent is indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency.

5.6.8 BD Multi-Check Control

BD™ Multi-Check Control is intended as a complete process control for immunophenotyping by flow cytometry. It is a control for antibody staining, red blood cell (RBC) lysis, instrument setup and performance, and data analysis on BD FACSLyric™, BD FACSCanto™ II, BD FACSCanto™, and BD FACSCalibur™ flow cytometers.

5.6.9 BD Multi-Check CD4 Low Control

BD™ Multi-Check CD4 Low Control is intended as a complete process control for immunophenotyping by flow cytometry. It is a control for antibody staining, red blood cell (RBC) lysis, instrument setup and performance, and data analysis on BD FACSLyric™, BD FACSCanto™ II, BD FACSCanto™, and BD FACSCalibur™ flow cytometers.

5.6.10 BD Trucount Tubes

BD Trucount™ tubes are intended for use with appropriated BD IVD reagent products on BD FACSLyric™, BD FACSVia™, BD FACSCanto™, BD FACSCanto™ II and BD FACSCalibur™ flow cytometers to determine absolute counts of leucocytes in erythrocyte-lysed whole blood.

5.6 Comparison of Technological Characteristics with the Predicate Device

A comparison of the similarities and differences between the subject device and the predicate device is presented in **Table 5-1** to **Table 5-4**

Table 5-1 Classification and Methodology

Feature/Attribute	Subject Device	Predicate Device
Device Classification and Product Code	• Automated Differential Cell Counter • Regulatory Class: II • Regulation Number: 21 CFR 864.5220 • Product Code: OYE	Same
Assay Methodology	Flow Cytometry	Same
Detection/Assay Principle	Immunofluorescence	Same
Monoclonal Antibody Reagents	• Multitest 6-color TBNK • Multitest IMK kit • Multitest CD3/CD8/CD45/CD4 • Multitest CD3/CD16 +CD56/CD45/CD19 All with optional Trucount tubes to provide identification and enumeration of Total CD3+, CD3+CD4+, CD3+CD8+, CD16+CD56+ and CD19+ percentages and absolute count results	Same
Specimen Type	Peripheral whole blood	Same
Sample Volume	50 µL	Same
Sample Preparation	Manual	• Manual • Automated (when used with optional accessory FACS Sample Prep Assistant III)

Table 5-2 Instrument and Software

Feature/Attribute	Subject Device	Predicate Device
Intended Use/ Indications for Use - Flow Cytometer	**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 Multitest 6-color TBNK, BD Multitest IMK kit, BD Multitest CD3/CD8/CD45/CD4, and BD Multitest CD3/CD16+CD56/CD45/CD19, all with optional BD Trucount tubes, are intended for use on the BD FACSLyric flow cytometer with peripheral whole blood for immunophenotyping. These reagents are indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency. These reagents determine the percentages and absolute counts of the following mature human lymphocyte subsets: BD Multitest 6-color TBNK with optional BD Trucount tubes • T lymphocytes ($CD3^+$) • B lymphocytes ($CD19^+$) • Natural killer (NK) lymphocytes ($CD3^-CD16^+$ and/or $CD56^+$) • Helper/inducer T lymphocytes ($CD3^+CD4^+$) • Suppressor/cytotoxic T lymphocytes ($CD3^+CD8^+$) BD Multitest IMK kit with optional BD Trucount tubes • T lymphocytes (CD3+) • B lymphocytes (CD19+) • Natural killer (NK) lymphocytes (CD3–CD16+ and/or CD56+) • Helper/inducer T lymphocytes (CD3+CD4+) • Suppressor/cytotoxic T lymphocytes (CD3+CD8+)	**The BD FACSCanto II flow cytometers (4-2-2 and 5-3 configurations)** function as part of a system with dedicated clinical software intended for use with cleared or approved in vitro diagnostic (IVD) assays that are indicated for use with the instrument for the identification and enumeration of human cell subsets. Only six detection channels using a blue (488 nm) and a red (633 nm) laser have been cleared for in vitro diagnostic use. For use with or without the BD FACS Sample Prep Assistant III. **The BD FACSCanto II flow cytometer (4-2 configuration)** is intended for use as an In Vitro Diagnostic device for identification and enumeration of lymphocyte subsets in human cells in suspension. • Immunophenotyping in clinical laboratories, using previously cleared in vitro diagnostic assays for flow cytometry. • Identification and enumeration of lymphocyte subsets in human cells in suspension. • For in vitro diagnostic use. • For use with or without the BD FACS Sample Prep Assistant III See intended use for BD Multitest reagents in **Table 5-4**.

Feature/Attribute	Subject Device	Predicate Device
	BD Multitest CD3/CD8/CD45/CD4 with optional BD Trucount tubes • T lymphocytes (CD3+) • Suppressor/cytotoxic T lymphocytes (CD3+CD8+) • Helper/inducer T lymphocytes (CD3+CD4+) BD Multitest CD3/CD16+CD56/CD45/CD19 with optional BD Trucount tubes • T lymphocytes (CD3+) • Natural killer (NK) lymphocytes (CD3–CD16+ and/or CD56+) • B lymphocytes (CD3–CD19+)	
Maximum Parameter Detectors	IVD detection channels – Six Fluorescence channels plus forward scatter and side scatter	Same
Forward Scatter Detection	Photodiode with built-in 488/10 bandpass filter	Same
Fluorescence and Side Scatter Detection	Side scatter and fluorescence • 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 to specially designed detector arrays • 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.	Same
Forward and Side Scatter Sensitivity	Enables separation of fixed platelets from noise.	Same
Sample Identification	Sample identification can be done through manual entry of sample information into the software or using an optional barcode reader.	Same
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), 6-color (4-2) • 2 laser (blue, red), 8-color (5-3) • 3-laser (blue, red, violet), 8-color (4-2-2)

Feature/Attribute	Subject Device	Predicate Device
	• 3-laser (blue, red, violet), 10-color (4-3-3) Only up to six detection channels using red and blue lasers are for IVD use.	 Only up to six detection channels using red and blue
Lasers Used for IVD Detection Channels	Blue • Wavelength: 488 nm • Optical power: 20 mW Red • Wavelength: 640 nm • Optical power: 40 mW	Blue • Wavelength: 488 nm • Optical power: 20 mW Red • Wavelength: 633 nm • Optical power: 17 mW
Electronics	Up to 35000 events/sec	Up to 10000 events/sec
Sample Introduction	• Manual loading onto the tube port of the flow cytometer • Automated loading through a multi-tube FACS Universal Loader (hold one 30 or 40-tube rack)	• Manual loading onto the tube port of the flow cytometer Automated loading through a multi-tube FACS Loader (carousel to hold up to 40 tubes)
Software	FACSuite Clinical software with the following Multitest assay modules: • Multitest 6-Color Assays • Multitest 4-Color Assays	FACSCanto Clinical software with Multitest 6-Color and Multitest 4-Color assays included as panels within the software
Sample Analysis	Automated gating of cellular populations by the software and manual adjustment by the user	Same
Results Reporting	Software- assisted report generation	Same
Fluidics	• Uses FACSFlow as the sheath fluid • Uses 10% bleach solution for system cleaning • System waste products are collected in the waste container (5L standard size)Uses FACSFlow as the sheath fluid	• Uses FACSFlow as the sheath fluid, together with FACS shutdown solution and FACS cleaning solution • System waste products are collected in the waste container (10 L standard size)

Table 5-3 Beads for Setup and Quality Control

Feature/ Attribute	Subject Device	Predicate Device
	Quality Control and Setup Beads	
Intended Use/ Indications for Use	**BD FC beads 7-color kit** The BD FC beads 7-color kit (BD FC beads), in conjunction with BD FACSuite Clinical software and BD CS&T beads, are used to establish fluorescence compensation for the BD FACSLyric flow cytometer. **BD CS&T beads** BD CS&T beads, in conjunction with BD FACSuite Clinical software, provide a standardized method for the quality control of optics, electronics, and fluidics, and for adjusting detector voltages and fluorescence compensation on the BD FACSLyric flow cytometer.	**BD FACS 7-Color Setup Beads** For in vitro diagnostic use on a BD FACSCanto flow cytometer with BD FACSCanto software. The beads are used to adjust fluorescent detector voltages, to set fluorescence compensation, and to monitor daily instrument performance.
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 • FC Beads are run every 2 months to measure and reset instrument spectral overlap values as part of the instrument setup.	• Daily QC performed using FACS 7-color setup • Daily instrument setup using FACS 7-color setup beads

Table 5-4 Monoclonal Antibody Reagents and Process Controls

Feature/ Attribute	Subject Device	Predicate Device
	Multitest 6-Color TBNK	
Intended Use/ Indications for Use	BD Multitest 6-color TBNK with optional BD Trucount tubes is intended for use with BD FACSLyric, BD FACSCanto II, and BD FACSCanto flow cytometers to determine the percentages and absolute counts of the following mature human lymphocyte subsets in peripheral whole blood for immunophenotyping: • T lymphocytes ($CD3^+$) • B lymphocytes ($CD19^+$) • Natural killer (NK) lymphocytes ($CD3^-CD16^+$ and/or $CD56^+$) • Helper/inducer T lymphocytes ($CD3^+CD4^+$) • Suppressor/cytotoxic T lymphocytes ($CD3^+CD8^+$) This reagent is indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency.	BD Multitest 6-color TBNK reagent with optional BD Trucount tubes is a six-color direct immunofluorescence reagent for use with BD FACSCanto and BD FACSCanto II flow cytometers to identify and determine the percentages and absolute counts of T, B, and natural killer (NK) cells as well as the CD4 and CD8 subpopulations of T cells in peripheral blood. BD Multitest 6-color TBNK reagent and BD Trucount tubes can be used with the BD FACS Loader.

Feature/ Attribute	Subject Device	Predicate Device
	Multitest IMK Kit	
Intended Use/ Indications for Use	BD Multitest IMK kit with optional BD Trucount tubes is intended for use with BD FACSLyric, BD FACSCanto II, BD FACSCanto , and BD FACSCalibur flow cytometers to determine the percentages and absolute counts of the following mature human lymphocyte subsets in peripheral whole blood for immunophenotyping: • T lymphocytes ($CD3^+$) • B lymphocytes ($CD19^+$) • Natural killer (NK) lymphocytes ($CD3^-CD16^+$ and/or $CD56^+$) • Helper/inducer T lymphocytes ($CD3^+CD4^+$) • Suppressor/cytotoxic T lymphocytes ($CD3^+CD8^+$) This reagent is indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency.	**Intended Use** MultiTESTCD3/CD16+56/CD45/CD19 reagent is a four-color reagent for identifying and enumerating percentages and absolute counts of T (CD3+), NK (natural killer) (CD3- CD16+CD56+), and B (CD3-CD19 +) lymphocyte subsets by direct immunofluorescence. The MultiTEST IMK contains the same MultiTEST CD3/CD16+CD56/CD45/CD19) reagent, MultiTEST CD3/CD8/CD45/CD4 reagent, and MultiTEST IMK Kit Lysing Solution. Helper/inducer T (CD3+CD4+) and suppresser/cytotoxic T (CD3+CD8+) lymphocyte subset percentages and absolute counts can be obtained from the MultiTEST CD3/CD8/CD45/CD4 reagent included in the kit. Subsets of lymphocytes are useful in managing some forms of immunodeficiency diseases. **Indications for Use** • For use with Becton Dickinson FACS flow cytometers equipped with a blue (488-nm) and red diode (635-nm) laser. • Monoclonal antibody reagents for identification and enumeration of mature human lymphocyte subsets in peripheral blood of normal individuals and patients with certain immune dysfunction. • MultiTEST CD3/CD16+56/CD45/CD19 provides percentages and absolute counts of T (CD3+), NK (CD3-CD16+CD56) and B (CD3-CD19+) lymphocytes. MultiTEST CD3/CD8/CD45/CD4 provides percentages and absolute counts of T (CD3+), helper/inducer T (CD3+CD4+) and suppressor/cytotoxic T (CD3+CD8+) lymphocytes. • For use with erythrocyte lysed whole blood without an isotype control. • To characterize and monitor forms of auto immune diseases, such as lupus. • To characterize and monitor congenital or acquired immunodeficiences, such as SCID or AIDS. For in vitro diagnostic use.

Feature/ Attribute	Subject Device	Predicate Device
	Multitest CD3/CD8/CD45/CD4	
Intended Use/ Indications for Use	BD Multitest CD3/CD8/CD45/CD4 with optional BD Trucount tubes is intended for use with BD FACSLyric, BD FACSCanto II, BD FACSCanto, and BD FACSCalibur flow cytometers to determine the percentages and absolute counts of the following mature human lymphocyte subsets in peripheral whole blood for immunophenotyping: • T lymphocytes ($CD3^+$) • Helper/inducer T lymphocytes ($CD3^+CD4^+$) • Suppressor/cytotoxic T lymphocytes ($CD3^+CD8^+$) This reagent is indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency.	**Intended Use** MultiTEST CD3/CD8/CD45/CD4 reagent is a four-color reagent for identifying and enumerating CD3+ T Lymphocytes, CD3+CD4+ helper/inducer, and CD3+CD8+ suppresser/cytotoxic T Lymphocyte subsets by direct immunofluorescence. Subsets of T Lymphocytes are useful in managing immunodeficiency diseases. To characterize and monitor congenital or acquired immunodeficiences, such as SCID or AIDS. **Indications for Use** • For the FACS family of flow cytometers equipped with a blue (488-nm) and a red diode (635-nm) laser. • A monoclonal antibody reagent for identification and enumeration of mature human T lymphocyte subsets in human peripheral blood. • For use with erythrocyte lysed whole blood. • To characterize and monitor forms of autoimmune diseases, such as lupus. • To characterize and monitor congenital or acquired immunodeficiences, such as SCID or AIDS. For in vitro diagnostic use.
	Multitest CD3/CD16+CD56/CD45/CD19	
Intended Use/ Indications for Use – Multitest Reagents	BD Multitest CD3/CD16+CD56/CD45/CD19 with optional BD Trucount tubes is intended for use with BD FACSLyric, BD FACSCanto II, BD FACSCanto, and BD FACSCalibur flow cytometers to determine the percentages and absolute counts of the following mature human lymphocyte subsets in peripheral whole blood for immunophenotyping: • T lymphocytes ($CD3^+$) • Natural killer (NK) lymphocytes ($CD3^-CD16+$ and/or $CD56^+$) • B lymphocytes ($CD3^-CD19^+$)	**Intended Use** MultiTESTCD3/CD16+56/CD45/CD19 reagent is a four-color reagent for identifying and enumerating percentages and absolute counts of T (CD3+), NK (natural killer) (CD3- CD16+CD56+), and B (CD3-CD19 +) lymphocyte subsets by direct immunofluorescence. The MultiTEST IMK contains the same MultiTEST CD3/CD16+CD56/CD45/CD19) reagent, MultiTEST CD3/CD8/CD45/CD4 reagent, and MultiTEST IMK Kit Lysing Solution. Helper/inducer T (CD3+CD4+) and suppresser/cytotoxic T (CD3+CD8+) lymphocyte subset percentages and absolute counts can be obtained from the MultiTEST CD3/CD8/CD45/CD4 reagent

Feature/ Attribute	Subject Device	Predicate Device
	This reagent is indicated for use in the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency.	included in the kit. Subsets of lymphocytes are useful in managing some forms of immunodeficiency diseases. **Indications for Use** • For use with Becton Dickinson FAC flow cytometers equipped with a blue (488-nm) and red diode (635-nm) laser. • Monoclonal antibody reagents for identification and enumeration of mature human lymphocyte subsets in peripheral blood of normal individuals and patients with certain immune dysfunction. • MultiTEST CD3/CD16+56/CD45/CD19 provides percentages and absolute counts of T (CD3+), NK (CD3-CD16+CD56) and B (CD3-CD19+) lymphocytes.
	Trucount Tubes	
Intended Use/ Indications for Use	BD Trucount tubes are intended for use with appropriated BD IVD reagent products on BD FACSLyric, BD FACSVia, BD FACSCanto II, BD FACSCanto and BD FACSCalibur flow cytometers to determine absolute counts of leucocytes in erythrocyte-lysed whole blood.	**Intended Use** TruCount Absolute Count Tubes are intended for use as an accessory to TriTEST in vitro diagnostics, such as that described in K965053 (CD3/CD4/CD45), to allow computation of positive cells per know volume of blood, using flow cytometry. **Indications for Use** • For use with FACS Loader • For use with in vitro diagnostic immunophenotyping reagents • For use in erythrocyte lysed whole blood For use to obtain absolute counts by flow cytometry
	Multi-Check Controls	

Feature/ Attribute	Subject Device	Predicate Device
Intended Use/ Indications for Use	BD Multi-Check Control is intended as a complete process control for immunophenotyping by flow cytometry. It is a control for antibody staining, red blood cell (RBC) lysis, instrument setup and performance, and data analysis on BD FACSLyric, BD FACSCanto II, BD FACSCanto, and BD FACSCalibur flow cytometers.	Whole Blood Flow Control (WBFC) is a stabilized preparation of human peripheral leukocytes and erythrocytes to be used as a control in the complete immunophenotyping process which includes: antibody staining, RBC lysis, instrument set-up and instrument performance.
	Multi-Check CD4 Low Control	
	BD Multi-Check CD4 Low Control is intended as a complete process control for immunophenotyping by flow cytometry. It is a control for antibody staining, red blood cell (RBC) lysis, instrument setup and performance, and data analysis on BD FACSLyric, BD FACSCanto II, BD FACSCanto, and BD FACSCalibur flow cytometers.	StatusFlowLo is intended as a complete process control for immunophenotyping by flow cytometry. It is a control for antibody staining, RBC lysis, instrument set-up, instrument performance and data analysis.

A summary of the comparison is included as follows:

The subject device is similar to the predicate device as follows:

- Used for identification and enumeration of human lymphocyte cell subsets
- Performs the same flow cytometric assays with the same Multitest reagents and the same process controls
- Uses the same Trucount Tubes with a known number of beads per sample volume to calculate absolute cell counts
- Based on multicolor fluorescence
- Uses red, blue and violet lasers to provide excitation illumination for the specific wavelengths of the fluorophores; only the red and blue are used in the Multitest assays.
- Uses dichroic mirrors to split fluorescence emissions into wavelength ranges for each fluorophore to be detected
- Uses photomultiplier tubes (PMTs) for the detection of fluorescence emission signal

The subject device differs from the predicate device as follows:

- Is available in four optical configurations: 3-1, 4-2, 4-2-2, and 4-3-3, whereas the Predicate Device is available in 3 optical configurations: 4-2, 4-2-2 and 5-3.
- Has a high powered red laser that yields higher detection sensitivity compared to the predicate device
- Instrument QC is performed using CS&T Beads and fluorescence compensation is established by using FC beads 7-color kit, whereas for the predicate device, FACS 7-color setup beads are used to adjust fluorescent detector voltages, to set fluorescence compensation, and to monitor daily instrument performance. The subject device measures more parameters and is capable of more accurately assessing the instrument performance.
- Uses the optional FACS Universal Loader to automate loading tubes in 30- or 40-tube rack, whereas the predicate device uses FACS Loader which accommodates up to 40 tubes in a carousel.
- Smaller footprint with no separate wet cart for fluidics and generates much lower noise output than the predicate device.

5.7 Performance Data

The following bench (**Table 5-5**) and clinical (**Table 5-6**) performance data were provided to support the substantial equivalency determination.

Table 5-5 Bench Performance Summary

Study	Standard/Reference	Objective	Results
Intra-instrument Optical Configuration Equivalency	N/A	To demonstrate system level performance equivalency across the 3-1 (4-color), 4-2 (6-color), 4-2-2 (8-color), and 4-3-3 (10-color) optical configurations of the FACSLyric flow cytometer as measured by QC and setup performance parameters generated utilizing CS&T beads and FC beads.	System level optical equivalency was demonstrated between the four configurations (3-1, 4-2, 4-2-2 and 4-3-3) of the FACSLyric system.
Inter-instrument Optical Configuration Equivalency	*CLSI EP09-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline- Third Edition*	To demonstrate performance equivalency between the 3-1 (4-color), 4-2 (6-color), 4-2-2 (8-color), and 4-3-3 (10-color) optical configurations of the FACSLyric flow cytometer through testing multiple instruments of different configurations (inter-instrument) using patient and normal donor samples stained with Multitest IMK kit and Multitest 6-Color TBNK in Trucount tubes.	The performance equivalency of the 6 IVD channels between the 3-1, 4-2, 4-2-2 and 4-3-3 optical configurations of the FACSLyric flow cytometer have been demonstrated.

Study	Standard/Reference	Objective	Results
Method Comparison	*CLSI EP09-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline- Third Edition*	• To determine the method bias between the FACSLyric system with Multitest reagents and the FACSCanto II system with Multitest reagents on the determination of CD3+, CD3+CD4+, CD3+CD8+, CD19+ and CD16+56+ percentage and absolute counts. • To demonstrate equivalency between FACSLyric Universal Loader (UL) acquisition and FACSLyric manual acquisition when using the Multitest IMK kit and Multitest 6-Color TBNK with Trucount tubes in the determination of CD3+, CD3+CD4+, CD3+CD8+, CD19+ and CD16+56+ percentage and absolute counts.	The method bias between the FACSLyric and the FACSCanto II, in the determination of CD3+, CD3+CD4+, CD3+CD8+, CD19+ and CD16+56+ percentage and absolute counts, met the acceptance criteria using the Multitest IMK kit and Multitest 6-Color TBNK with Trucount tubes. In addition, equivalency between the FACSLyric UL acquisition and Manual acquisition was demonstrated.
Within-site Precision	*CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition*.	To evaluate the within-site precision performance of FACSLyric system using the Multitest IMK kit and Multitest 6-Color TBNK with Trucount tubes.	All acceptance criteria were met. The within-site precision performance of FACSLyric system using the Multitest IMK kit and Multitest 6-Color TBNK with Trucount tubes satisfied the within-run and total precision performance requirements.
Whole Blood Repeatability	*CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition*.	To verify repeatability performance across all the FACSLyric instruments of different configurations, using whole blood from patient and normal donor samples, stained with the Multitest IMK kit and Multitest 6-Color TBNK with Trucount tubes.	Repeatability performance was demonstrated across all the instruments with different configurations. All lymphocyte subsets met %CV and SD acceptance criteria.
Linearity	*CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.*	To evaluate the linear range of the FACSLyric system using the Multitest IMK kit and Multitest 6-Color TBNK with Trucount tubes.	Acceptable linear ranges have been established for each lymphocyte subset for each of the Multitest reagents on FACSLyric system.

Study	Standard/Reference	Objective	Results
Sample Carryover	*CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard- Second Edition*	To determine the percent sample carryover based on acquisition of three highly concentrated samples immediately followed by acquisition of three low concentrated samples on FACSLyric system.	All the results met the acceptance criteria of system carryover less than or equal to 0.1% for low carryover and less than or equal to 0.5% for standard carryover on all three FACSLyric instruments. To meet the low carryover requirement the results demonstrated that only a single SIT flush was required.
Reagent Carryover	*CLSI H26-A2 Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard- Second Edition*.	To verify the capability of the FACSLyric system to acquire samples with minimal reagent carryover.	Results met the acceptance criteria were met. The amount of reagent being carried over is found to be well below the amount of reagent required for effective staining of the sample.
Detection Capability of LoB and LoD	*CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline-Second Edition.*	To evaluate the limit of blank (LoB) and limit of detection (LoD) of the FACSLyric system with Multitest IMK kit and Multitest 6-Color TBNK with Trucount tubes.	The detection capability parameters for the limit of blank (LoB) and limit of detection (LoD) of the FACSLyric system were established for BD Multitest reagents. For CD4 lymphocyte subset absolute counts of each of the reagents, the established LoB and LoD were less than 50 cells/µL.
Detection Capability of LoQ	*CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline-Second Edition.*	To evaluate the limit of quantitation (LoQ) of the FACSLyric system using Multitest IMK kit and Multitest 6-Color TBNK, both with Trucount tubes.	The LoQ of the FACSLyric system with Multitest reagents was established for the CD3+, CD3+CD4+, CD3+CD8+, CD19+, CD16+CD56+ and CD45+ lymphocyte subsets. The acceptance criteria were met and the LOQ is less than 50 cells/µL for CD4 lymphocyte subset absolute counts.
Setup and QC Performance	N/A	To verify that Setup & QC Performance of the FACSLyric system meets the pre-defined specifications.	All the Setup & QC performance results of the FACSLyric system met the acceptance criteria

Study	Standard/Reference	Objective	Results
Setup and QC Stability	N/A	To verify the stability of system level Setup & QC on the FACSLyric system.	All the system level Setup & QC stability performance results on the FACSLyric system met the pre-defined specifications.

Table 5-6 Clinical Performance Summary

Study	Standard/Reference	Testing Approach	Results
Method Comparison	*CLSI EP09-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline- Third Edition*	To evaluate performance equivalence of the FACSLyric system and the FACSCanto II system on the determination of lymphocyte subsets using the Multitest 6-Color TBNK and Multitest IMK kit, both with Trucount tubes, using remnant, de-linked patient specimens.	A total of 332 specimens were enrolled for testing with Multitest 6-Color TBNK (297 evaluable), and 368 specimens were enrolled for Multitest IMK kit (336 evaluable) at 5 clinical sites. The acceptance criteria for all lymphocyte subsets were met for the FACSLyric system. The differences of the results between all the specimens and the non-manipulated specimens were very minimal, and no bias trend was observed. Additional analysis per site and by different EDTA anticoagulant formulations (EDTA-K2 vs EDTA-K3) in the blood collection tubes also showed minimal difference with no trend observed.
Inter-laboratory Reproducibility	*CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition*.	To evaluate inter-laboratory reproducibility for the FACSLyric system on the determination of lymphocyte subsets using the Multitest 6-Color TBNK and Multitest IMK kit in Trucount tubes with a single lot of Streck CD-Chex Plus process control material.	Inter-laboratory reproducibility was carried out at four clinical sites. The variability for within run, between run, between day, between site and total precision per reagent and lymphocyte subset was evaluated. The 97.5% one-sided confidence interval (CI) on the within run and total precision was estimated and compared to the acceptance criteria for each lymphocyte subset.
Reference Intervals	*CLSI EP28-A3c How to Define and Determine Reference Intervals in the Clinical Laboratory, Approved Guideline-Second Edition.*	To re-establish the reference intervals of a normal male and female adult cohort, free of hematological abnormality, using the FACSLyric system for the Multitest 6-Color TBNK and Multitest IMK kit, both with Trucount tubes, on determination of lymphocyte subsets using prospectively procured and de-linked donor specimens at one study site.	A total of 136 subjects were enrolled (134 evaluable for Multitest 6-Color TBNK and 130 evaluable for Multitest IMK kit) from one clinical site. Reference Intervals for all lymphocyte subsets in the Multitest 6-Color TBNK and Multitest IMK kit were established for the FACSLyric system. Differences were observed between genders, but these differences are not clinically significant.

Study	Standard/Reference	Testing Approach	Results
Specimen Stability	*N/A*	To generate data to support stability of venous whole blood with EDTA anticoagulant when testing the Multitest 6-Color TBNK and Multitest IMK kit, both with Trucount tubes, on the FACSLyric system using prospectively procured and de-linked patient specimens from at least two study sites.	A total of 227 specimens were enrolled for each of the reagents from the two clinical sites. 180 specimens were evaluable for Multitest 6-Color TBNK and 186 were evaluable for Multitest IMK kit. The results from the study support the claim of up to 24 hours Age of Blood and 6 hours Age of Stain for Multitest 6-Color TBNK, and up to 48 hours Age of Blood and 24 hours Age of Stain for Multitest IMK kit (include Multitest CD3/CD8/CD45/CD4 and Multitest CD3/CD16+CD56/CD45/CD19) on FACSLyric system.

5.8 Conclusion

The FACSLyric flow cytometer demonstrates substantial equivalency to the FACSCanto II system with Multitest reagents.