October 20, 2026

BD Biosciences
Jeff Yarch
Senior Regulatory Affairs Specialist
155 N. Mccarthy Blvd.
Milpitas, California 95035

Re: K260215
Trade/Device Name: BD OneFlow LST
BD OneFlow B-CLPD T1
BD FACSLyric Flow Cytometer, 8-color [4-2-2], 10-color [4-3-3], 12-color (4-3-5)
Regulation Number: 21 CFR 864.7010
Regulation Name: Flow cytometric test system for hematopoietic neoplasms
Regulatory Class: Class II
Product Code: PWD, OYE
Dated: September 14, 2026
Received: September 14, 2026

Dear Jeff Yarch:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and
Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260215

Please provide the device trade name(s).

BD OneFlow LST
BD OneFlow B-CLPD T1
BD FACSLyric Flow Cytometer 8-color (4-2-2) 10-color (4-3-3) 12-color (4-3-5)

Please provide your Indications for Use below.

BD OneFlow LST
BD OneFlow LST (Lymphoid Survey Tube) is intended for in vitro diagnostic use as a panel of fluorochrome-conjugated antibodies for qualitative flow cytometric immunophenotyping of mature lymphocyte populations on the BD FACSLyric flow cytometer using BD FACSuite Clinical application. BD OneFlow LST is used as an aid in identification of hematologically abnormal mature B-cell, mature T-cell, and mature NK-cell lineages in patients having, or suspected of having, lymphoid lineage malignancies or neoplasms when used in conjunction with lineage-specific BD OneFlow reagents.
BD OneFlow LST can be used with peripheral blood specimens collected in EDTA (K2 or K3) or heparin (sodium or lithium) tubes, bone marrow specimens collected in K2 EDTA tubes, and lymph node specimens. The results should be interpreted by a pathologist or equivalent professional in conjunction with other clinical or laboratory findings.
BD OneFlow LST provides multi-parameter, qualitative results for the following antigens: CD3, CD4, CD5, CD8, CD19, CD20, CD38, CD45, CD56, Igκ, Igλ, and TCRγ/δ.

BD OneFlow B-CLPD T1
BD OneFlow B-CLPD T1 (B-cell Chronic Lymphoproliferative Disease Tube 1) is intended for in vitro diagnostic use as a panel of fluorochrome-conjugated antibodies for qualitative flow-cytometric immunophenotyping of mature B-lymphocyte populations on the BD FACSLyric flow cytometer using BD FACSuite Clinical application.
When used in conjunction with BD OneFlow LST, BD OneFlow B-CLPD T1 is used as an aid in the diagnosis of patients having, or suspected of having, a B-cell non-Hodgkin's lymphoma including B-cell chronic lymphocytic leukemia (B-CLL).
BD OneFlow B-CLPD T1 can be used with peripheral blood specimens collected in EDTA (K2 or K3) or heparin (sodium or lithium) tubes, bone marrow specimens collected in K2 EDTA tubes, and lymph node specimens. The results should be interpreted by a pathologist or equivalent professional in conjunction with other clinical or laboratory findings.
BD OneFlow B-CLPD T1 provides multi-parameter, qualitative results for the following antigens: CD10, CD19, CD20, CD23, CD43, CD45, CD79b, and CD200.

The BD FACSLyric flow cytometer, 8-color (4-2-2), 10-color (4-3-3), 12-color (4-3-5)
The BD FACSLyric flow cytometer is intended for use as an in vitro diagnostic device for the following:
•Immunophenotyping using up to eight fluorescence detection channels and two light scatter channels using a violet (405-nm), 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.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

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

Date of Summary: October 19, 2026

1. Submitted By

Becton, Dickinson and Company
BD Biosciences
155 North McCarthy Boulevard
Milpitas, California 95035 USA

Contact Person: Jeff Yarch
Telephone: (530) 518-8444
Email: jeff.yarch@bd.com

2. Device

Trade Name/Device Name:	BD OneFlow LST BD OneFlow B-CLPD T1
Classification:	Class II
Device Classification:	Flow Cytometric Test System for Hematopoietic Neoplasms
Regulation Medical Specialty:	Hematology
Product Code:	PWD
Regulation Number:	21 CFR§864.7010

Trade Name/Device Name:	BD FACSLyric Flow Cytometer, 8-color (4-2-2), 10-color (4-3-3), 12-color (4-3-5)
Classification:	Class II
Device Classification:	Flow Cytometric Reagents and Accessories
Regulation Medical Specialty:	Hematology
Product Code:	OYE
Regulation Number:	21 CFR§864.5220

3. Predicate Device Information

Trade Name/Device Name:	ClearLLab 10C Panels (B, T, M1, M2) (K183592)
Classification:	Class II
Device Classification:	Flow Cytometric Test System for Hematopoietic Neoplasms
Regulation Medical Specialty:	Hematology
Product Code:	PWD
Regulation Number:	21 CFR§864.7010

Reference Devices

Trade Name/Device Name:	BD FACSLyric Flow Cytometer with Assay Modules (K201814) BD FC Beads 7-Color Kit (K170974)
Classification:	Class II
Device Classification:	Flow Cytometric Reagents and Accessories
Regulation Medical Specialty:	Hematology
Product Code:	OYE
Regulation Number:	21 CFR§864.5220

4. Device Description

BD OneFlow LST (Lymphoid Survey Tube) and BD OneFlow B-CLPD T1 (B-Cell Chronic Lymphoproliferative Disease Tube 1) are part of a flow cytometric test system for identification of hematopoietic neoplasms. The devices consist of reagents for immunophenotyping of human cells in relation to the level of expression of specific cellular markers. These reagents are used as an aid in the differential diagnosis of hematologically abnormal patients having or suspected of having hematopoietic neoplasms.

The purpose of this bundled traditional 510(k) submission is to receive market authorization for BD OneFlow LST and BD OneFlow B-CLPD T1, and for updates to a flow cytometry system on which these devices can be run. Scope of this submission also includes:

1. Updates to the BD FACSLyric Flow Cytometer Indications for Use statement for use with eight cleared IVD fluorescence detection channels and use of a violet laser. The BD FACSLyric Flow Cytometer is an automated differential cell counter that uses lasers to generate fluorescent signals, multiple optical configurations to capture signals, software for qualitative data analysis, and reagents for instrument setup. The device is intended to be used for immunophenotyping and in vitro diagnostics.

2. Introduction of new BD OneFlow LST and BD OneFlow B-CLPD T1 Assay Modules, which are used in conjunction with BD FACSuite Clinical Application. These assay modules analyze flow cytometry standard (FCS) files and graphically display data for qualitative assessment. The BD OneFlow Assay Modules contain acquisition and analysis templates such as plots, gates, and population statistics. The identification and classification of cell populations through the BD OneFlow Assay Modules are interpreted by a pathologist or equivalent professional in conjunction with other clinical or laboratory findings.

3. Introduction of three new fluorescent beads (BD FC Beads APC-H7, BD FC Beads V450, BD FC Beads V500-C), which are required for set up of the eight FACSLyric Flow Cytometer fluorescence detection channels to be used with OneFlow devices. BD FC Beads APC-H7, BD FC Beads V450, and BD FC Beads V500-C all consist of polystyrene beads that are coupled to fluorochromes. These beads are provided as dried reagents in clear plastic single-use tubes. Prior to use, BD FC Beads require rehydration with dilution buffer. The BD FC Beads are used to generate spillover values (SOVs) across

fluorescence detection channels. The SOVs are used to compensate the fluorescence detection channels.

BD FC Beads V450, in conjunction with BD FACSuite Clinical application and BD CS&T Beads, are used to establish fluorescence compensation for the BD FACSLyric flow cytometer.

BD FC Beads V500-C, in conjunction with BD FACSuite Clinical application and BD CS&T Beads, are used to establish fluorescence compensation for the BD FACSLyric flow cytometer.

BD FC Beads APC-H7, in conjunction with BD FACSuite Clinical application and BD CS&T Beads, are used to establish fluorescence compensation for the BD FACSLyric flow cytometer.

5. Indications for Use

BD OneFlow LST

BD OneFlow LST (Lymphoid Survey Tube) is intended for in vitro diagnostic use as a panel of fluorochrome-conjugated antibodies for qualitative flow cytometric immunophenotyping of mature lymphocyte populations on the BD FACSLyric flow cytometer using BD FACSuite Clinical application.

BD OneFlow LST is used as an aid in identification of hematologically abnormal mature B-cell, mature T-cell, and mature NK-cell lineages in patients having, or suspected of having, lymphoid lineage malignancies or neoplasms when used in conjunction with lineage-specific BD OneFlow reagents.

BD OneFlow LST can be used with peripheral blood specimens collected in EDTA (K2 or K3) or heparin (sodium or lithium) tubes, bone marrow specimens collected in K2 EDTA tubes, and lymph node specimens. The results should be interpreted by a pathologist or equivalent professional in conjunction with other clinical or laboratory findings.

BD OneFlow LST provides multi-parameter, qualitative results for the following antigens: CD3, CD4, CD5, CD8, CD19, CD20, CD38, CD45, CD56, Igκ, Igλ, and TCRγ/δ.

BD OneFlow B-CLPD T1

BD OneFlow B-CLPD T1 (B-cell Chronic Lymphoproliferative Disease Tube 1) is intended for in vitro diagnostic use as a panel of fluorochrome-conjugated antibodies for qualitative flow-cytometric immunophenotyping of mature B-lymphocyte populations on the BD FACSLyric flow cytometer using BD FACSuite Clinical application.

When used in conjunction with BD OneFlow LST, BD OneFlow B-CLPD T1 is used as an aid in the diagnosis of patients having, or suspected of having, a B-cell non-Hodgkin's lymphoma including B-cell chronic lymphocytic leukemia (B-CLL).

BD OneFlow B-CLPD T1 can be used with peripheral blood specimens collected in EDTA (K2 or K3) or heparin (sodium or lithium) tubes, bone marrow specimens collected in K2 EDTA tubes, and lymph node specimens. The results should be interpreted by a pathologist or equivalent professional in conjunction with other clinical or laboratory findings.

BD OneFlow B-CLPD T1 provides multi-parameter, qualitative results for the following antigens: CD10, CD19, CD20, CD23, CD43, CD45, CD79b, and CD200.

BD FACSLyric Flow Cytometer, 8-color (4-2-2), 10-color (4-3-3), 12-color (4-3-5)

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

- Immunophenotyping using up to eight fluorescence detection channels and two light scatter channels using a violet (405-nm), 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. Comparison of Technological Characteristics with the Predicate Device

Subject and Predicate Devices are similar in design, materials, energy source and other features. The Subject and Predicate Devices have the same basic technological characteristics, as described in the following tables.

Table 1 compares the technological characteristics of Subject Devices and the Predicate Device flow cytometric test systems. Subject and Predicate Devices are flow cytometric test systems for identification of hematopoietic neoplasms and consist of reagents for immunophenotyping of human cells in relation to the level of expression of specific cellular markers. Differences in the Subject and Predicate Devices' Indications for Use do not result in a new intended use and these differences do not affect the safety and effectiveness of the device when used as labeled. Table 2 compares the technological characteristics of the BD FACSLyric Flow Cytometer Subject Device to a Reference Device. Table 3 compares the technological characteristics of the BD FC Beads APC H7, BD FC Beads V450, and BD FC Beads V500-C Subject Devices to a Reference Device.

Table 1. Comparison Between Subject and Predicate Device Flow Cytometric Test Systems

Characteristic	Subject Devices: BD OneFlow LST and BD OneFlow B-CLPD T1 Flow Cytometric Test System	Predicate Device: ClearLLab 10C Panels (B, T, M1, M2) (K183592)
Device Classification and Product Code	Regulation Number: 21 CFR§864.7010, flow cytometric test system for hematopoietic neoplasms Product Code: PWD, flow cytometric test system for hematopoietic neoplasms	
Intended Use	In vitro diagnostic device for immunophenotyping	
Indications for Use	**BD OneFlow LST** BD OneFlow LST (Lymphoid Survey Tube) is intended for in vitro diagnostic use as a panel of fluorochrome-conjugated antibodies for qualitative flow cytometric immunophenotyping of mature lymphocyte populations on the BD FACSLyric flow cytometer using BD FACSuite Clinical application. BD OneFlow LST is used as an aid in identification of hematologically abnormal mature B-cell, mature T-cell, and mature NK-cell lineages in patients having, or suspected of having, lymphoid lineage malignancies or neoplasms when used in conjunction with lineage-specific BD OneFlow reagents. BD OneFlow LST can be used with peripheral blood specimens collected in EDTA (K2 or K3) or heparin (sodium or lithium) tubes, bone marrow specimens collected in K2 EDTA tubes, and lymph node specimens. The results should be interpreted by a pathologist or	**ClearLLab 10C Panels (B, T, M1, M2):** The ClearLLab 10C Panels are intended for in vitro diagnostic use for qualitative identification of cell populations by multiparameter immunophenotyping on the Navios and Navios EX flow cytometers. These reagents are used as an aid in the differential diagnosis of hematologically abnormal patients having, or suspected of having, the following hematopoietic neoplasms: chronic leukemia, acute leukemia, non-Hodgkin lymphoma, myeloma, myelodysplastic syndrome (MDS), and/or myeloproliferative neoplasms (MPN). The reagents can be used with peripheral whole blood (collected in K_2EDTA, ACD or Heparin), bone marrow (collected in K2EDTA, ACD or Heparin), and lymph node specimens. Interpretation of the results should be confirmed by a pathologist or equivalent in conjunction with other clinical and laboratory findings. These reagents provide multiparameter, qualitative results for the surface antigens listed below: • ClearLLab 10C B Cell Tube: Kappa, Lambda, CD10, CD5, CD200, CD34, CD38, CD20, CD19, CD45 • ClearLLab 10C T Cell Tube: TCRγδ, CD4, CD2, CD56, CD5, CD34, CD3, CD8, CD7, CD45

Characteristic	Subject Devices: BD OneFlow LST and BD OneFlow B-CLPD T1 Flow Cytometric Test System	Predicate Device: ClearLLab 10C Panels (B, T, M1, M2) (K183592)
	equivalent professional in conjunction with other clinical or laboratory findings. BD OneFlow LST provides multi-parameter, qualitative results for the following antigens: CD3, CD4, CD5, CD8, CD19, CD20, CD38, CD45, CD56, Igκ, Igλ, and TCRγ/δ. **BD OneFlow B-CLPD T1** BD OneFlow B-CLPD T1 (B-cell Chronic Lymphoproliferative Disease Tube 1) is intended for in vitro diagnostic use as a panel of fluorochrome-conjugated antibodies for qualitative flow cytometric immunophenotyping of mature B-lymphocyte populations on the BD FACSLyric flow cytometer using BD FACSuite Clinical application. When used in conjunction with BD OneFlow LST, BD OneFlow B-CLPD T1 is used as an aid in the diagnosis of patients having, or suspected of having, a B-cell non-Hodgkin's lymphoma including B-cell chronic lymphocytic leukemia (B-CLL). BD OneFlow B-CLPD T1 can be used with peripheral blood specimens collected in EDTA (K2 or K3) or heparin (sodium or lithium) tubes, bone marrow specimens collected in K2 EDTA tubes, and lymph node specimens.	• ClearLLab 10C M1 Cell Tube: CD16, CD7, CD10, CD13, CD64, CD34, CD14, HLADR, CD11b, CD45 • ClearLLab 10C M2 Cell Tube: CD15, CD123, CD117, CD13, CD33, CD34, CD38, HLA-DR, CD19, CD45

<table>
<tr><th>Characteristic</th><th>Subject Devices: BD OneFlow LST and BD OneFlow B-CLPD T1 Flow Cytometric Test System</th><th>Predicate Device: ClearLLab 10C Panels (B, T, M1, M2) (K183592)</th></tr>
<tr><td></td><td>The results should be interpreted by a pathologist or equivalent professional in conjunction with other clinical or laboratory findings.

BD OneFlow B-CLPD T1 provides multi-parameter, qualitative results for the following antigens: CD10, CD19, CD20, CD23, CD43, CD45, CD79b, and CD200.</td><td></td></tr>
<tr><td>Reagent Tubes Composition</td><td><u>BD OneFlow CLPD Limited Panel</u>

(bold markers are the same across devices)
<table><tr><th>BD OneFlow LST Tube</th><th>BD OneFlow B-CLPD T1 Tube</th></tr><tr><td>CD8 and Igλ (LAMBDA)</td><td>CD23</td></tr><tr><td>CD56 and Igκ (KAPPA)</td><td>CD10</td></tr><tr><td>CD5</td><td>CD79b</td></tr><tr><td>CD19 and TCRγ/δ</td><td>CD19</td></tr><tr><td>CD3</td><td>CD200</td></tr><tr><td>CD38</td><td>CD43</td></tr><tr><td>CD20 and CD4</td><td>CD20</td></tr><tr><td>CD45</td><td>CD45</td></tr></table></td><td><u>ClearLLab 10C Panels</u>
<table><tr><th>B Panel</th><th>T Panel</th><th>M1 Panel</th><th>M2 Panel</th></tr><tr><td>LAMBDA</td><td>CD4</td><td>CD7</td><td>CD123</td></tr><tr><td>CD10</td><td>CD2</td><td>CD10</td><td>CD117</td></tr><tr><td>CD5</td><td>CD56</td><td>CD13</td><td>CD13</td></tr><tr><td>CD200</td><td>CD5</td><td>CD64</td><td>CD33</td></tr><tr><td>CD34</td><td>CD34</td><td>CD34</td><td>CD34</td></tr><tr><td>CD38</td><td>CD7</td><td>CD14</td><td>CD38</td></tr><tr><td>CD20</td><td>CD8</td><td>HLA-DR</td><td>HLA-DR</td></tr><tr><td>CD19</td><td>CD3</td><td>CD11b</td><td>CD19</td></tr><tr><td>KAPPA</td><td>TCRγδ</td><td>CD16</td><td>CD15</td></tr><tr><td>CD45</td><td>CD45</td><td>CD45</td><td>CD45</td></tr></table></td></tr>
<tr><td>Reagent Form</td><td colspan="2">Dry unitized form (one test per tube)</td></tr>
<tr><td>Storage Conditions</td><td>5°C or 25°C</td><td>18–30 °C</td></tr>
<tr><td>Setup Reagents:</td><td>BD CS&T Beads</td><td>Flow-Set Pro Fluorospheres:</td></tr>
</table>

Characteristic	Subject Devices: BD OneFlow LST and BD OneFlow B-CLPD T1 Flow Cytometric Test System	Predicate Device: ClearLLab 10C Panels (B, T, M1, M2) (K183592)
Standardization		
Setup Reagents: Optical alignment and fluidics	BD CS&T Beads	Flow-Check Pro Fluorospheres
Setup Reagents: Lyse and Fixation	BD FACS Lysing Solution (10X)	IOTest 3 Fixative Solution IOTest 3 Lysing Solution
Setup Reagents: Sample Preparation	Wash and prepare samples manually	
Reagents for Color Compensation	BD FC Beads 7-Color Kit, BD FC Beads APC-H7, BD FC Beads V450, BD FC Beads V500-C, see Table 3	ClearLLab Compensation Kit with ClearLLab Compensation Beads
Instrument	BD FACSLyric Flow Cytometer (with red, blue, and violet lasers), see Table 2.	Navios Flow Cytometers (with red, blue, and violet lasers)
Software Analysis	BD FACSuite Clinical Application with the BD OneFlow™ Assay Modules, see Table 2	Kaluza C data analysis software

Table 2. Comparison of BD FACSLyric Flow Cytometer to Reference Device

Characteristic	Subject Device: BD FACSLyric Flow Cytometer (4-2-2, 4-3-3, 4-3-5 optical configurations), with BD OneFlow™ Assay Modules	Reference Device: BD FACSLyric™ Flow Cytometer (K201814)
Device Classification and Product Code	Regulation Number: 21 CFR 864.5220, Automated differential cell counter Product Code: OYE, flow cytometric reagents and accessories	
Indications for Use	The BD FACSLyric Flow Cytometer, 8-color (4-2-2), 10-color (4-3-3), 12-color (4-3-5) The BD FACSLyric flow cytometer is intended for use as an in vitro diagnostic device for the following: • Immunophenotyping using up to eight fluorescence detection channels and two light scatter channels using a violet (405-nm), 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.
Assay Methodology	Flow Cytometry	
Detection/Assay Principle	Immunofluorescence	
Electronics	Up to 35000 events/sec	
Forward Scatter Detection	Photodiode with built in 488/10 bandpass filter	
Fluorescence and Side Scatter Detection	• Side scatter and fluorescence • Reflective optics with single transmission bandpass filter in front of each photomultiplier tube (PMT) • High performance PMT modules for all fluorescence and side scatter channels	

Characteristic	Subject Device: BD FACSLyric Flow Cytometer (4-2-2, 4-3-3, 4-3-5 optical configurations), with BD OneFlow™ Assay Modules	Reference Device: BD FACSLyric™ Flow Cytometer (K201814)
	• Light collected by objective lens is delivered by fiber optics especially designed detector arrays • The cuvette flow cell is gel-coupled by refractive optical gel to the fluorescence objective lens (1.2 NA) for optimal collection efficiency	
Maximum parameter detectors	IVD detection channels-8 fluorescence channels, plus forward scatter and side scatter	IVD detection channels-6 fluorescence channels, plus forward scatter and side scatter
Optical Configurations	• 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), 12-color (4-3-5) configuration Only up to eight detection channels using red and blue lasers are for IVD use	• 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), 12-color (4-3-5) configuration Only up to six detection channels using red and blue lasers are for IVD use
Laser used for IVD detection channels	Blue: • Wavelength: 488 nm • Optical power: 20 mW Red: • Wavelength: 640 nm • Optical power: 40 mW Violet: • Wavelength: 405 nm • Optical power: 40 mW	Blue: • Wavelength: 488 nm • Optical power: 20 mW Red: • Wavelength: 640 nm • Optical power: 40 mW
Fluidics	BD FACSLyric Flow Cytometer fluidics • Uses BD FACSFlow as the sheath fluid • Uses 10% bleach solution for system cleaning	
Firmware	CMS Firmware	
Loader	BD FACS Universal Loader (optional)	

Characteristic	Subject Device: BD FACSLyric Flow Cytometer (4-2-2, 4-3-3, 4-3-5 optical configurations), with BD OneFlow™ Assay Modules	Reference Device: BD FACSLyric™ Flow Cytometer (K201814)
Sample Introduction	• Manual loading onto the tube port of the flow cytometer • Automated loading through a multi-tube FACS Universal Loader	
Quality Control	• Daily Performance QC (PQC) performed using BD CS&T beads • Characterization QC (CQC) is performed every 6 months using BD CS&T beads. It includes all the measurements performed in daily PQC along with additional more detailed measurements and an automatic laser alignment. CQC is initially performed to set up an instrument performance baseline.	
Software	BD FACSuite Clinical Application (version 1.5) was developed to allow plug-ins to the existing application architecture. BD OneFlow Assays Installer CLPD Panel installs the BD OneFlow LST and B-CLPD T1 Assay Modules onto the BD FACSuite Clinical Application so they can be run on BD FACSLyric Flow Cytometers.	BD FACSuite™ Clinical Application (version 1.4) was developed to allow plug-ins to the existing application architecture.
Results Reporting	Software-assisted report generation facilitated by assay modules	
Sample Preparation	Manual	
Dimensions	Cytometer (W × D × H) 63.3 × 57.9 × 57.9 cm (24.93 × 22.8 × 22.8 in.)	

Table 3. Comparison of BD FC Beads APC-H7, V450, V500-C to Reference Device

Characteristic	Subject Devices: BD FC Beads APC-H7, BD FC Beads V450, BD FC Beads V500-C	Reference Device: BD® FC Beads 7-Color Kit (K170974)
Device Classification and Product Code	Regulation Number: 21 CFR 864.5220, Automated differential cell counter Product Code: OYE, flow cytometric reagents and accessories	
Indications for Use	BD FC Beads V450, in conjunction with BD FACSuite Clinical application and BD CS&T Beads, are used to establish fluorescence compensation for the BD FACSLyric flow cytometer. BD FC Beads V500-C, in conjunction with BD FACSuite Clinical application and BD CS&T Beads, are used to establish fluorescence compensation for the BD FACSLyric flow cytometer. BD FC Beads APC-H7, in conjunction with BD FACSuite Clinical application and BD CS&T Beads, are used to establish fluorescence compensation for the BD FACSLyric flow cytometer.	The BD FC Beads 7-Color kit (BD FC beads), in conjunction with BD FACSuite Clinical software and BD CS&T beads, is used to establish fluorescence compensation for the BD FACSLyric flow cytometer.
Instrument Setup	BD FC Beads are run every 60 days to measure and reset instrument spectral overlap values as part of the instrument setup.	
Fluorophores	APC-H7, V450, V500-C	FITC, PE, PerCP-Cy5.5, PE-Cy7, APC, APC-Cy7
Lasers Used	Red, Violet	Blue, Red
Material/Size	3µm polystyrene beads	

7. Performance Data

Table 4 summarizes the non-clinical performance studies conducted to demonstrate the substantial equivalence of the Subject Devices' safety and effectiveness compared to the Predicated Device's safety and effectiveness. Table 5 summarizes the clinical performance study conducted to demonstrate the substantial equivalence of the Subject Devices' safety and effectiveness compared to the Predicated Device's safety and effectiveness.

Table 4. Analytical Performance Testing

Study	Standard/Reference	Objective	Result
Within-Laboratory and Multi-Site Precision Evaluation	CLSI EP05-A3	Demonstrate the precision of the assays with control samples	Pass
Specimen Repeatability and Operator-to-Operator Precision Evaluation	CLSI EP05-A3	Demonstrate the precision of the assays with intended use samples	Pass
Sample Carryover	CLSI H26-A2 CLSI H44-A2	Demonstrate specimen/sample carryover meets performance specifications	Pass
Stability Evaluation of Age of Blood and Age of Stain of Intended Use Samples	CLSI EP12-A2 CLSI EP25-Ed2E	Demonstrate stability of intended use specimens from time of specimen collection and time between specimen staining (prepared sample) and sample acquisition on the flow cytometer	Pass
Evaluation of Cell Range	CLSI H26-A2 CLSI H44-A2	Demonstrate the ability of the assays to reliably identify cell populations according to performance specifications	Pass
Detection Capability (Limit of Detection)	CLSI EP17-A2	Demonstrate the ability of the assays to discriminate low level abnormal cell populations from normal cell populations	Pass
Limit of Blank	International Clinical Cytometry Society (ICCS) and International Council for Standardization in Hematology (ICSH) Practice Guidelines (Wood et al. (Cytometry Part B (Clinical Cytometry) 84B:315-323 (2013))	Determine the highest apparent background observed in normal cell populations	Pass
Reference Range	CLSI EP28-A3c	Demonstrate the expected frequency of lymphocyte subpopulations in the peripheral blood (PB) samples of apparently healthy donors	Pass

Study	Standard/Reference	Objective	Result
Determination of Equivalency between Anticoagulants	CLSI EP-09-A3	Demonstrate equivalent performance of peripheral blood and bone marrow specimens collected in claimed anticoagulants	Pass
Reagent Carryover	CLSI H26-A2	Demonstrate reagent carryover meets performance specifications	Pass
BD OneFlow™ and BD® FC Beads Stability	CLSI EP25	Demonstrate reagent stability	Pass
BD® FC Beads Performance	Not Applicable	Demonstrate the beads meet performance specifications	Pass
Verification of Detector Linearity	Not Applicable	Verify the linearity of the BD FACSLyric Flow Cytometer photomultiplier tubes (PMTs) within the required range of operation	Pass

Table 5. Clinical Performance Testing

	Subject Devices - BD OneFlow LST and BD OneFlow B-CLPD T1	**Predicate Device** - ClearLLab 10C Panels (B, T, M1, M2)
Study Description	Evaluate the equivalency of BD OneFlow LST and BD OneFlow B-CLPD T1 in identifying an abnormal or normal phenotype vs. the site's final clinical diagnosis of malignant or non-malignant outcome based on the current standard of care.	Evaluate the clinical accuracy of the ClearLLab 10C Panels in identifying an abnormal or normal phenotype vs. the site's clinical diagnosis of malignant or non-malignant outcome from the current standard of care

Endpoints	• Primary Endpoints, All Evaluated Sample Types
	  ○ Sensitivity
	  ○ Specificity
	• Secondary Endpoints, Peripheral Blood Samples
	  ○ Sensitivity
	  ○ Sensitivity
		• Primary Endpoints, All Sample Types
		  ○ Sensitivity
		  ○ Specificity
		• Secondary Endpoints, Peripheral Blood Samples
		  ○ Sensitivity
		  ○ Sensitivity

Results	The final clinical data analysis demonstrated acceptable sensitivity and specificity in support of the intended use.	All end points **PASSED** acceptance criteria

The clinical performance testing demonstrated that BD OneFlow LST and BD OneFlow B-CLPD T1 provide acceptable clinical performance for the proposed intended use. Differences in the clinical performance study design and analysis between the subject and predicate devices do not raise different questions of safety or effectiveness and do not affect the determination of substantial equivalence.

8. Conclusion

In this submission the Subject Devices BD OneFlow LST and BD OneFlow B-CLPD T1 flow cytometric test system have been compared to the legally marketed Predicate Device, ClearLLab 10C Panels (B, T, M1, M2).

The Subject and Predicate Devices have the same intended use and similar basic technological characteristics. Where the devices differ in technological characteristics, the differences do not raise different questions of safety or effectiveness.

The methods used to test the clinical and analytical performance of the Subject Devices are comparable to Predicate and Reference Devices. Results from these performance studies demonstrate the Subject Devices are safe and effective for their intended use. The Subject Devices in this submission are therefore substantially equivalent to the Predicate Device.