

## 510(k) Summary

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

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### 5.1 Submitted By

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### 5.2 Trade Name/Device Name: **BD FACSVia™ System with BD Leucocount Reagent Assay**

Device Name: BD FACSVia System with Leucocount Reagent Assay

Classification: Class II  
Device Classification: Flow Cytometric Reagents and Accessories  
Classification Name: Automated Differential Cell Counter  
Classification Panel: Hematology and Pathology Devices Panel  
Classification Code: OYE  
Regulation: 21 CFR 864.5220

### 5.3 Predicate Devices of the System:

**Table 5-1** compares the description of cleared predicate devices with the proposed description of subject devices within the BD FACSVia System.

Table 5-1. Description of Cleared Predicate Devices and Proposed Subject Devices

| 510(k)   | Cleared Predicate Device Description   | Proposed Subject Device Description |
|----------|--|-------------------------------------|
| K973483  | FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set | BD FACSVia System Flow Cytometer    |
| BK970046 | BD Leucocount Reagent  |                                     |
| BK970046 | BD Leucocount Reagent  | BD Leucocount Kit                   |
| BK000035 | R&D Leuko-Reduced RBC Control  | BD Leucocount RBC Control Kit       |
| BK000036 | R&D Leuko-Reduced Plt Control  | BD Leucocount PLT Control Kit       |
| K000897  | CaliBRITE PerCP-Cy5.5 Beads and FACSComp Software                              | BD CS&T Beads                       |

## 5.4 Predicate Device Selection Rationale

- 5.4.1** The FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set was chosen as a predicate because both the subject and predicate devices use the same immunoassay and process controls, and both have the same scientific fundamental flow cytometer instrument requirements and functions. The predicate FACSComp Software is incorporated into the FACSCalibur flow cytometer, and both the FACSComp Software and CaliBRITE Beads were validated using the FACSCalibur flow cytometer. The subject device FACSVia System was validated using the FACSCalibur flow cytometer as the predicate.
- 5.4.2** R&D Leuko-Reduced RBC Control and R&D Leuko-Reduced Plt Control were chosen as the predicates for the BD Leucocount RBC Control Kit and BD Leucocount PLT Control Kit used on the BD FACSVia System since both controls kits are identical and have equivalent functions and performance to both the predicate and subject systems. BD Leucocount RBC and PLT Control Kits are identical products to their predicates R&D Leuko-Reduced RBC and Plt Controls (BK000035 and BK000036); only the trade names have changed.
- 5.4.3** CaliBRITE™ PerCP-Cy5.5 Beads were chosen as the predicate for the BD™ CS&T Beads since both are instrument quality control beads used in the same application. The CaliBRITE PerCP-Cy5.5 Beads were validated for use on the BD FACSCalibur System, and the BD CS&T Beads were validated for use on the BD FACSVia System. The two systems monitor or verify similar parameters, bead position, CV and channel sensitivity or separation.
- The beads of the two systems have similar monitoring performance. The beads used with the FACSCalibur set PMT voltages and monitor

instrument performance over time. The beads used with the FACSVia verify the instrument performance over time.

- The beads of the two systems warn the user if the instrument departs from the target PMT voltages. The FACSCalibur adjusts the PMT voltages to the bead position at the target value, and the change in voltage is monitored over time. The FACSVia PMT voltages are set at manufacturing, and the system monitors the bead position over time. The user is warned if the system departs from the target position. Changes in bead position are monitored.

## 5.5 Basic Description of the Device

The BD FACSVia™ System with Leucocount Reagent Assay consists of the components, reagents, and accessories below. In accordance with *FDA Guidance for Industry and FDA Staff, Bundling Multiple Devices or Multiple Indications in a Single Submission*, dated June 22, 2007, this 510(k) submission includes the bundle of the device (BD FACSVia System) with its components (BD CS&T Beads) and reagents (BD Leucocount reagent assay and process controls).

- BD FACSVia flow cytometer with dedicated workstation
- Fluidics and maintenance components
- BD FACSVia clinical software
- BD™ CS&T Beads for instrument Quality Control (QC)
- Clinical reagent assay BD Leucocount™ Kit, which includes the BD Trucount™ Tubes
- BD Leucocount RBC Control Kit, BD Leucocount PLT Control Kit, and BD Leucocount Combo Control Kit
- Optional accessory BD FACSVia Loader for automated loading of samples
- Optional accessory BD FACSLink driver for transfer of patient information and results to and from a Laboratory Information System (LIS)
- Optional accessory barcode reader

Leucocyte reduced blood components are routinely used for transfusions. Some patients undergoing transfusions will benefit from the removal of leucocytes, since residual donor leucocytes present in cellular blood components have been linked to a variety of transfusion complications. These complications include febrile nonhemolytic transfusion reaction, transmission of leucotropic viruses (such as cytomegalovirus) and HLA alloimmunization. The BD Leucocount reagent assay is used by blood centers and clinical laboratories where quality control of the leucoreduced blood products are needed.

Leucoreduction is an effective means of decreasing exposure to donor leucocytes. The two most widely used methods for leucoreduction are filtration and apheresis. High-performance filters combine size-retention, electrostatic attachment and receptor-ligand interactions resulting in less than  $5 \times 10^6$  leucocytes per unit transfused. Manufacturers of apheresis equipment have developed platelet-

harvesting technologies that collect platelets with minimum leucocyte contamination.

The FACSVia System will combine ease of use and affordability for clinicians into a small, compact flow cytometer. The FACSVia comes with a dedicated PC workstation with monitor, keyboard and mouse. The FACSVia reagent assays, components and accessories are described in **Table 5-2**.

Table 5-2. FACSVia Reagent Assays, Components, and Accessories

| Product               | Description  |
|-----------------------|--|
| <b>FACSVIA SYSTEM</b> |  |
| BD FACSVia™ System    | <ul style="list-style-type: none"> <li>• FACSVia flow cytometer includes a blue laser, six detection parameters with a range of fixed detector voltages of 96V to 250V (50Hz to 60Hz), fluidics and maintenance components, and optics.</li> <li>• FACSVia accessory kit includes:               <ul style="list-style-type: none"> <li>○ 12 x 75 mm sample tubes (pack of 125 tubes)</li> <li>○ Sample Injection Port (SIP) unclog syringe kit</li> <li>○ Fluidics bottle tray assembly with fluidics bottles and harness</li> <li>○ Power cord and power supply</li> <li>○ Two month preventative maintenance kit, which consists of the following:                   <ul style="list-style-type: none"> <li>▪ 2 peristaltic pump tubing</li> <li>▪ 3 fluid bottle filters</li> <li>▪ 1 inline sheath filter</li> </ul> </li> </ul> </li> <li>• Fluid bottle filters are used to prevent particles five microns or smaller from getting into the fluidic path (Sheath bottle, Detergent Solution bottle, and BD FACSClean bottle). Inline sheath filter filters the sheath fluid. The peristaltic pump tubing is a component of the flow cytometer pumps. These components are replaced by the user every two months or when 35 L of the sheath fluid has been used.</li> <li>• FACSVia System does not have wireless or WiFi capability.</li> </ul> |

| Product                        | Description  |
|--------------------------------|--|
| <b>WORKSTATION - DEDICATED</b> |  |
| Workstation Bundle             | <p>USB-compatible personal computer (PC) with monitor, keyboard, and mouse. The PC is a desktop workstation with the following features:</p> <ul style="list-style-type: none"> <li>• Microsoft Windows 7</li> <li>• 64-bit multi-core processor running at 2.9 GHz or faster</li> <li>• 26 GB free hard disk space after operating system and software application installation</li> <li>• 8 GB RAM</li> <li>• 3 USB ports, version 2.0 or greater</li> <li>• DVD drive</li> <li>• Software CD</li> <li>• Windows-ready mouse and keyboard</li> <li>• 19-in monitor with 1280 x 1024 or higher resolution</li> <li>• PC dimensions: <ul style="list-style-type: none"> <li>○ Height: 33 cm (13 in)</li> <li>○ Width: 10.2 cm (4 in)</li> <li>○ Depth: 38.1 cm (15 in)</li> </ul> </li> </ul>  |
| BD FACSVia™ clinical software  | <p>The software does not come pre-installed on the PC, but rather is installed by a BD Field Service Engineer (FSE) as part of system installation. Customers are provided with the software installer and reagent assay test definition files on CD to reinstall the software, if necessary.</p> <p>The software (also referred to as the user interface) controls the cytometer, acquires samples, analyzes results, and reports data.</p> <p>The software also provides access via the Help Menu to the BD FACSVia System Safety and Limitations and BD Leucocount Application Guide and the instrument instructions for use. The Help Menu does not require internet access.</p> <p>Software CD includes:</p> <ul style="list-style-type: none"> <li>• BD FACSVia clinical software installer <ul style="list-style-type: none"> <li>○ Installs the software, including the QC module.</li> </ul> </li> <li>• BD Leucocount assay test definition file <ul style="list-style-type: none"> <li>○ Enables the user to run the BD Leucocount assay on the FACSVia System.</li> </ul> </li> <li>• Assay and Help installer <ul style="list-style-type: none"> <li>○ Installs the BD Leucocount assay test definition.</li> <li>○ Installs BD FACSVia System Instructions for Use, BD FACSVia System Safety and Limitations, BD Leucocount Application Guide for the</li> </ul> </li> </ul> |

| Product                               | Description  |
|---------------------------------------|--|
|                                       | <p style="text-align: center;">BD FACSVia System.</p> <ul style="list-style-type: none"> <li>• Help document files will be in the English language. <ul style="list-style-type: none"> <li>○ BD FACSVia System Instructions for Use</li> </ul> </li> </ul> <p>BD FACSVia Leucocount Application Guide for the FACSVia System</p> |
| <b>QC BEADS</b>                       |  |
| BD™ CS&T Beads                        | Designed for use with FACSVia clinical software for the verification of optical and fluidic performance and to adjust compensation on the FACSVia flow cytometer. BD CS&T Beads are used to run instrument QC daily, ensuring that the instrument is performing properly before running samples.                                 |
| <b>FLUIDICS COMPONENTS</b>            |  |
| BD™ Sheath Additive                   | Bacteriostatic reagent that is added to 0.2-µm filtered deionized water to make Sheath Fluid.  |
| BD™ Detergent Solution Concentrate    | Detergent solution concentrate for fluidics system. Diluted solution is used during the automatic fluidics cleaning cycle when the system is shut down.  |
| BD™ FACSClean Solution                | Cleaning solution for fluidics system. Used to perform Sample Injection Port (SIP) cleaning and during the automatic fluidics cleaning cycle when the system is shut down.   |
| BD™ Extended Flow Cell Clean Solution | Cleaning solution specifically for SIP and flow cell. Used to perform extended flow cell clean cycle. This cycle allows for soaking of the components most commonly exposed to sample.   |
| <b>REAGENT ASSAY</b>                  |  |
| BD Leucocount™ Kit                    | <p>Designed for counting residual white blood cells (rWBCs) in leucoreduced blood products.</p> <p>Kit contains one bottle of Leucocount reagent for 50 samples and 50 Trucount tubes. Each test requires 400 µL of Leucocount reagent.</p>  |
| BD Leucocount™ RBC Control Kit        | <p>Used to monitor methods for enumeration of residual leucocytes in leucoreduced red blood cell (RBC) products.</p> <p>Kit contains 2 vials of RBC controls (1 RBC low and 1 RBC high).</p>   |
| BD Leucocount™ PLT Control Kit        | <p>Used to monitor methods for enumeration of residual leucocytes in leucoreduced platelet (PLT) products.</p> <p>Kit contains 2 vials of PLT controls (1 PLT low and 1 PLT high).</p>   |

| <b>Product</b>                   | <b>Description</b>   |
|----------------------------------|--|
| BD Leucocount™ Combo Control Kit | Combination of Leucocount RBC and PLT Control Kits.<br>Kit contains 2 vials of RBC controls (1 RBC low and 1 RBC high) and 2 vials of PLT controls (1 PLT low and 1 PLT high). |
| <b>OPTIONAL ACCESSORIES</b>      |  |
| BD FACSVia™ Loader               | Automates the sample loading step.   |
| BD FACSLink™                     | Provides a bi-directional connection to the Laboratory Information System (LIS) for transfer of patient information and results between the BD FACSVia clinical software.      |
| Barcode Reader                   | Handheld imager that connects to the PC through a universal serial bus (USB) port and reads barcodes.  |

## 5.6 Comparison to the Predicates

### 5.6.1 Intended Use

Intended Use statements are noted below and in **Table 5-3**. Similarities between the subject and predicate intended use for each predicate, and a comparison of the main system features are highlighted in light blue in **Table 5-3**.

#### 5.6.1.1 BD FACSVia™ Flow Cytometer System

Functions with dedicated BD FACSVia™ clinical software using a blue laser (488 nm) with two fluorescent detection channels (FL1 for BD Trucount™ Tube and FL2 for the BD Leucocount™ reagent).

The system is intended for flow cytometric enumeration of residual white blood cells (rWBCs) in leucoreduced blood products with the following reagents and controls:

- The BD Leucocount™ Kit  
Consists of Leucocount reagent (propidium iodide fluorescent dye) and Trucount tubes and is intended for enumerating residual white blood cells (rWBCs) in leucoreduced blood products.
- The BD Leucocount™ RBC Control Kit  
Consists of Red Blood Cells (RBC) Low and RBC High process controls intended for use with the BD Leucocount Kit to monitor the process for enumeration of residual leucocytes in leucoreduced RBC products including dilution, staining, instrument set up and white blood cell (WBC) enumeration.

- The BD Leucocount™ PLT Control Kit  
Consists of Platelet (PLT) Low and PLC High process controls intended for use with the BD Leucocount Kit to monitor the process for enumeration of residual leucocytes in leucoreduced Platelet products including dilution, staining, instrument set up and white blood cell (WBC) enumeration.
- The BD™ CS&T Beads  
For verification of optical and fluidic performance and to adjust compensation on the flow cytometer.

For *in vitro* diagnostic use.

#### **5.6.1.2 BD Leucocount™ Kit**

Consists of Leucocount reagent (propidium iodide fluorescent dye) and Trucount tubes and is intended for use with the BD FACSCalibur™, BD FACSort™, BD FACScan™, and BD FACSVia™ flow cytometer systems, or for a flow cytometer equipped with a 488 nm argon-ion laser able to threshold on FL2, for enumerating residual white blood cells (rWBCs) in leucoreduced blood products.

For *in vitro* diagnostic use.

#### **5.6.1.3 BD Leucocount™ RBC Control Kit**

Consists of Red Blood Cells (RBC) Low and RBC High process controls intended for use with the BD Leucocount™ Kit to monitor the process for enumeration of residual leucocytes in leucoreduced RBC products including dilution, staining, instrument set up and white blood cell (WBC) enumeration.

For *in vitro* diagnostic use.

#### **5.6.1.4 BD Leucocount™ PLT Control Kit**

Consists of Platelet (PLT) Low and PLC High process controls intended for use with the BD Leucocount™ Kit to monitor the process for enumeration of residual leucocytes in leucoreduced Platelet products including dilution, staining, instrument set up and white blood cell (WBC) enumeration.

For *in vitro* diagnostic use.



### 5.6.1.5 BD™ CS&T Beads

Intended for use on the BD FACSVia™ flow cytometer system with the BD FACSVia™ clinical software for the verification of optical and fluidic performance and to adjust compensation on the flow cytometer.

For in vitro diagnostic use.

### 5.6.2 Technological Characteristics

The technological differences between the BD FACSVia System and the BD FACSCalibur System are in the areas of the PMT voltages as part of instrument QC and the fluidics system. The primary differences are:

- BD FACSVia System is a fixed voltage system and does not set PMT voltages as part of instrument QC, whereas the BD FACSCalibur System sets PMT voltages during instrument QC.
- The BD FACSVia System uses peristaltic pumps to provide a non-pressurized, “push/pull” fluidics system, whereas the BD FACSCalibur System uses a pressurized fluidics system.
- For sample analysis, the BD FACSVia System uses automatic calculation by the BD FACSVia clinical software to determine the absolute counts for residual White Blood Cells; whereas, the BD FACSCalibur System requires manual calculation by the user.
  - A new feature not provided by BD FACSCalibur System is the template is locked to prevent creation of new or deletion of existing plots and regions or alteration of calculations.
- FACSVia System has automated report creation; whereas, the FACSCalibur System requires manual report creation.

The performance of the BD FACSVia System using Leucocount Reagent Assay has been verified and validated to be substantially equivalent to the predicate FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set. The predicate FACSComp Software is incorporated into the FACSCalibur flow cytometer, and both the FACSComp Software and CaliBRITE Beads were validated using the FACSCalibur flow cytometer.

Table 5-3. Similarities Between Subject and Predicate Intended Use Statements and System Main Features

| Feature/ Attribute  | FACSVia System using BD Leucocount Reagent Assay  | FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set (K973483)<br><br>BD Leucocount™ Reagent (BK970046)  |
|---|---|--|
| Intended Use/ Indications for Use – Flow Cytometer System |   |  |
| Intended Use/ Indications for Use                         | <p><b>BD FACSVia™ Flow Cytometer System</b><br/>Functions with dedicated BD FACSVia™ clinical software using a blue laser (488 nm) with two fluorescent detection channels (FL1 for BD Trucount™ Tube and FL2 for the BD Leucocount™ reagent).</p> <p>The system is intended for flow cytometric enumeration of residual white blood cells (rWBCs) in leucoreduced blood products with the following reagents and controls:</p> <ul style="list-style-type: none"> <li>• The BD Leucocount™ Kit<br/>Consists of Leucocount reagent (propidium iodide fluorescent dye) and Trucount tubes and is intended for enumerating residual white blood cells (rWBCs) in leucoreduced blood products.</li> <li>• The BD Leucocount™ RBC Control Kit<br/>Consists of Red Blood Cells (RBC) Low and RBC High process controls intended for use with the BD Leucocount Kit to monitor the process for enumeration of residual</li> </ul> | <p><b>FACSComp™ Software and CaliBRITE™ Beads for use in Flow Cytometer Instrument Set (K973483)</b><br/>For the FACS® family of flow cytometers (FACScan, FACSsort and FACSCalibur).<br/>An accessory device for instrument setup prior to performing reticulocyte enumeration and immunophenotyping.<br/>For adjusting instrument settings: aligning the signal from the blue and the optional red laser (FL4 Option), setting the photomultiplier tube (PMT) voltages, and monitoring instrument performance over time.<br/>For automatically setting the fluorescence compensation of the detectors to adjust for spectral overlap of fluorescent signals.<br/>For monitoring the sensitivity of the side scatter (SSC) and fluorescence (FL1, FL2, FL3, and FL4) detectors and verifying adequate separation of system noise from forward scatter (FSC) signals.<br/>For in vitro diagnostic use.</p> |

Table 5-3. Similarities Between Subject and Predicate Intended Use Statements and System Main Features

| Feature/ Attribute | FACSVia System using BD Leucocount Reagent Assay  | FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set (K973483)<br><b>BD Leucocount™ Reagent (BK970046)</b>  |
|--------------------|---|---|
|                    | <p>leucocytes in leucoreduced RBC products including dilution, staining, instrument set up and white blood cell (WBC) enumeration.</p> <ul style="list-style-type: none"> <li>• The BD Leucocount™ PLT Control Kit Consists of Platelet (PLT) Low and PLC High process controls intended for use with the BD Leucocount Kit to monitor the process for enumeration of residual leucocytes in leucoreduced Platelet products including dilution, staining, instrument set up and white blood cell (WBC) enumeration.</li> <li>• The BD™ CS&amp;T Beads For verification of optical and fluidic performance and to adjust compensation on the flow cytometer.</li> </ul> <p>For <i>in vitro</i> diagnostic use.</p> | <p><b>BD Leucocount™ Reagent (BK970046)</b></p> <ul style="list-style-type: none"> <li>• For enumeration of residual white blood cells in leucoreduced platelet packs and red blood cell units.</li> <li>• For the FACS family of flow cytometers (FACSCalibur™, FACSort™, FACScan™) or for a flow cytometer equipped with a 488 nm argon-ion laser able to threshold on FL2.</li> <li>• For <i>in vitro</i> diagnostic use.</li> </ul> |

Table 5-3. Similarities Between Subject and Predicate Intended Use Statements and System Main Features

| Feature/ Attribute   | FACSVia System using BD Leucocount Reagent Assay  | FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set (K973483)<br><br>BD Leucocount™ Reagent (BK970046)   |
|--|---|---|
| Intended Use/ Indications for Use – Reagent Assay Components |   |   |
| Intended Use/ Indications for Use                            | <p><b>BD Leucocount™ Kit</b><br/>                     Consists of Leucocount reagent (propidium iodide fluorescent dye) and Trucount tubes and is intended for use with the BD FACSCalibur™, BD FACSort™, BD FACScan™, and BD FACSVia™ flow cytometer systems, or for a flow cytometer equipped with a 488 nm argon-ion laser able to threshold on FL2, for enumerating residual white blood cells (rWBCs) in leucoreduced blood products.<br/>                     For <i>in vitro</i> diagnostic use.</p> | <p><b>BD Leucocount™ Reagent (BK970046)</b></p> <ul style="list-style-type: none"> <li>• For enumeration of residual white blood cells in leucoreduced platelet packs and red blood cell units.</li> <li>• For the FACS family of flow cytometers (FACSCalibur™, FACSort™, FACScan™) or for a flow cytometer equipped with a 488 nm argon-ion laser able to threshold on FL2.</li> <li>• For <i>in vitro</i> diagnostic use.</li> </ul> |

Table 5-3. Similarities Between Subject and Predicate Intended Use Statements and System Main Features

| <b>Feature/ Attribute</b>                                 | <b>FACSVia System using BD Leucocount Reagent Assay</b>   | <b>FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set (K973483)</b><br><b>BD Leucocount™ Reagent (BK970046)</b>   |
|---|---|---|
| Intended Use/ Indications for Use                         | <b>BD Leucocount™ RBC Control Kit</b><br>Consists of Red Blood Cells (RBC) Low and RBC High process controls intended for use with the BD Leucocount™ Kit to monitor the process for enumeration of residual leucocytes in leucoreduced RBC products including dilution, staining, instrument set up and white blood cell (WBC) enumeration.<br>For <i>in vitro</i> diagnostic use. | <b>R&amp;D Leuko-Reduced RBC Control (BK000035)</b><br>R&D Leuko-Reduced RBC Control is used to monitor methods for enumeration of residual leukocytes in leuko-reduced RBC products, including the dilution and staining process, method setup and WBC enumeration.      |
| Intended Use/ Indications for Use                         | <b>BD Leucocount™ PLT Control Kit</b><br>Consists of Platelet (PLT) Low and PLC High process controls intended for use with the BD Leucocount™ Kit to monitor the process for enumeration of residual leucocytes in leucoreduced Platelet products including dilution, staining, instrument set up and white blood cell (WBC) enumeration.<br>For <i>in vitro</i> diagnostic use.   | <b>R&amp;D Leuko-Reduced Plt Control (BK000036)</b><br>R&D Leuko-Reduced Plt Control is used to monitor methods for enumeration of residual leukocytes in leuko-reduced platelet products, including the dilution and staining process, method setup and WBC enumeration. |
| Intended Use/ Indications for Use – Quality Control Beads |   |   |
| Intended Use/ Indications for Use                         | <b>BD™ CS&amp;T Beads</b><br>Intended for use on the BD FACSVia™ flow cytometer system with the BD FACSVia™ clinical software for the verification of optical   | <b>CaliBRITE™ PerCP-Cy5.5 Beads and FACSComp™ Software (K000897)</b><br><ul style="list-style-type: none"> <li>• For the FACS family of Flow cytometers (FACStrak™, FACScan™, FACSort™ and</li> </ul>   |

Table 5-3. Similarities Between Subject and Predicate Intended Use Statements and System Main Features

| Feature/ Attribute                     | FACSVia System using BD Leucocount Reagent Assay   | FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set (K973483)<br><b>BD Leucocount™ Reagent (BK970046)</b>  |
|--|--|---|
|  | <p>and fluidic performance and to adjust compensation on the flow cytometer.</p> <p>For <i>in vitro</i> diagnostic use.</p>  | <p>FACSCalibur™).</p> <ul style="list-style-type: none"> <li>• An accessory device for instrument setup prior to performing reticulocyte enumeration and immunophenotyping.</li> <li>• For adjusting instrument settings: aligning the signal from the blue and the optional red laser (FL4 Option), setting the photomultiplier tube (PMT) voltages, and monitoring instrument performance over time.</li> <li>• For automatically setting the fluorescence compensation of the detectors to adjust for spectral overlap of fluorescent signals.</li> <li>• For monitoring the sensitivity of the side scatter (SSC) and fluorescence (FL1, FL2, FL3, and FL4) detectors and verifying adequate separation of system noise from forward scatter (FSC) signals.</li> <li>• For <i>in vitro</i> diagnostic use.</li> </ul> |
| Device Classification and Product Code | <p>Automated Differential Cell Counter</p> <ul style="list-style-type: none"> <li>• Regulatory Class: II</li> <li>• Regulation Number: 21 CFR 864.5220</li> <li>• Product Code: OYE</li> </ul> | <p>Automated Differential Cell Counter</p> <ul style="list-style-type: none"> <li>• Regulatory Class: II</li> <li>• Regulation Number: 21 CFR 864.5220</li> <li>• Product Code: OYE (originally 510(k) cleared as GKZ)</li> </ul>   |

Table 5-3. Similarities Between Subject and Predicate Intended Use Statements and System Main Features

| <b>Feature/ Attribute</b>       | <b>FACSVia System using BD Leucocount Reagent Assay</b>  | <b>FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set (K973483)</b><br><b>BD Leucocount™ Reagent (BK970046)</b>  |
|---------------------------------|--|--|
| Device Size                     | Cytometer with fluid bottles <ul style="list-style-type: none"> <li>○ Length: 27.9 cm (11 in)</li> <li>○ Width: 54.6 cm (21.5 in)</li> <li>○ Height: 41.9 cm (16.5 in)</li> </ul> Cytometer with BD FACSVia Loader <ul style="list-style-type: none"> <li>○ Length: 50.8 cm (20 in)</li> <li>○ Width: 35.6 cm (14 in)</li> <li>○ Height: 20.3 cm (8 in)</li> </ul> | Cytometer - FACSCalibur <ul style="list-style-type: none"> <li>○ Length: 91.4 cm (36 in)</li> <li>○ Depth: 61.5 cm (24.2 in)</li> <li>○ Height: 67.3 cm (26.5 in), or 124.5 cm (49 in) with cover open</li> </ul> Loader does not change size of cytometer. Fluid bottles are located within system. |
| Power Requirements              | Input Voltage: 100 to 240 VAC, 50 to 60 Hz<br><br>The FACSVia System has a Universal Supply that can accept 100 to 240 VAC.  | FACSCalibur Flow Cytometer:<br>Input Voltage: 115 VAC / 50 Hz<br>To operate the FACSCalibur System where AC Voltages are greater than 115 VAC, a Power Conditioner (Step Down Transformer) is required. The Power Conditioner takes the 230 VAC Power and steps it down to 115 VAC.                  |
| Assay Menu (FDA Cleared Assays) | Enumerating leucocytes of nucleated cells that contain DNA in leucoreduced blood products.   |  |
| Sample Type                     | Leucoreduced human whole blood product   |  |
| Sample Volume                   | Minimum 100 uL leucoreduced blood product  |  |
| Sample Preparation              | User should utilize their standard laboratory manual pipetting practice to prepare samples in BD Trucount tubes for loading onto the flow cytometer. User should follow instrument instructions for use for optional loader of samples.  |  |

Table 5-3. Similarities Between Subject and Predicate Intended Use Statements and System Main Features

| <b>Feature/ Attribute</b> | <b>FACSVia System using BD Leucocount Reagent Assay</b>   | <b>FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set (K973483)</b><br><b>BD Leucocount™ Reagent (BK970046)</b>   |
|---------------------------|---|---|
| Assay Methodology         | Flow cytometry using fluorescent reagent Propidium Iodide to stain cellular DNA of nucleated cells with Trucount beads for absolute count.  |   |
| Sample Analysis           | BD FACSVia clinical software requires manual adjustment of regions to identify residual white blood cells and Trucount beads. Automatic calculation by the FACSVia clinical software determines the absolute counts for residual White Blood Cells. New feature not provided by FACSCalibur is the template is locked to prevent creation of new or deletion of existing plots and regions or alteration of calculations. | FACSCalibur Flow Cytometer: BD Cell Quest Pro software requires manual adjustment of regions to identify residual white blood cells and Trucount beads. Manual calculation by the user to determine absolute counts for residual White Blood Cells is described in the Product Insert Sheet. Expression Editor can be used to combine statistics in user-entered mathematical expression for calculating absolute counts. |
| Sample Introduction       | Non Pressurized push-pull fluidic system  | FACSCalibur Flow Cytometer: Pressurized fluidic system  |
| Optics Principles         | Fluorescence excitation of stained cells in flow stream illuminated by the laser; and fluorescence emission measured by PMTs. Forward scatter and side scatter detectors are pin diodes. Six detectors are arranged in a pie configuration around a flow cell to maximize light collection, where the laser intersects the sample stream.   |   |
| IVD Excitation            | Blue Laser: 488 nm solid state, 21mW  | FACSCalibur Flow Cytometer: Blue Laser: 488 nm air-cooled argon-ion laser, 15 mW  |



Table 5-3. Similarities Between Subject and Predicate Intended Use Statements and System Main Features

| <b>Feature/ Attribute</b>                 | <b>FACSVia System using BD Leucocount Reagent Assay</b>  | <b>FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set (K973483)</b><br><b>BD Leucocount™ Reagent (BK970046)</b>   |
|---|--|---|
|   |  | Red Laser: 635 nm diode laser, 10mW   |
| Optical Detection                         | Fluorescence emission measured by high-performance photomultipliers. Side scatter and forward scatter detectors are high performance PIN diodes.   | FACSCalibur Flow Cytometer: Side Scatter and Fluorescence measured by high-performance photomultipliers. Forward Scatter detector is a high-performance solid state silicon diode.  |
| Electronics                               | 32-bit microprocessor based system. USB interface between computer and system. Digital signal processing done in FPGA (field-programmable gate array).   | FACSCalibur Flow Cytometer: 32-bit microprocessor based system. Custom analog electronics for signal processing.  |
| Fluidics                                  | Uses filtered deionized water as sheath fluid  | Uses FACSFlow (saline solution)   |
| Fluidics System                           | Consists of two peristaltic pumps to provide a non-pressurized, “push/pull” fluidics system which control the flow of sample, sheath fluid, cleaning solutions, and waste during data acquisition, instrument start up and instrument shut down. | FACSCalibur Flow Cytometer: Consists of a pressurized pinch valve assembly which controls the flow of sample, saline sheath fluid, and waste fluids during sample data acquisition. |
| Instrument Setup and Quality Control (QC) | Setup: Semi-automated setup using BD FACSVia clinical software with BD CS&T beads to quality control optics, electronics, fluidics, and for adjusting compensation.  | FACSCalibur Flow Cytometer: Setup: Semi-automated setup using BD FACSComp™ software with BD Calibrite beads for setting PMT voltages, fluorescence                                  |

Table 5-3. Similarities Between Subject and Predicate Intended Use Statements and System Main Features

| Feature/ Attribute      | FACSVia System using BD Leucocount Reagent Assay  | FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set (K973483)<br><b>BD Leucocount™ Reagent (BK970046)</b>                                    |
|-------------------------|---|---|
|                         |   | compensation, and checking instrument sensitivity.  |
| PMT Voltage Control     | During manufacturing of the BD FACSVia instruments, each voltage detector is set to place fluorescent beads in defined positions. The PMT voltage settings are then fixed and the software is not able to modify the PMT voltages. BD FACSVia clinical software checks settings during instrument QC with established target values encoded in the BD CS&T bead lot file. | FACSCalibur Flow Cytometer:<br>BD FACSComp software automatically adjusts PMT settings to match established target values encoded in the software during instrument QC. |
| Software                | BD FACSVia clinical software on PC.   | FACSCalibur Flow Cytometer:<br>BD FACSComp software and BD CellQuest Pro software both on PC.   |
| Results Reporting       | Automated report creation   | Manual report creation  |
| Optional Loader         | BD FACSVia Loader, dedicated loader for BD FACSVia System   | BD FACS Loader  |
| Optional Barcode Reader | Handheld imager connects to PC through a universal serial bus (USB) port.   |   |
| Optional BD FACSLink    | Software driver designed for BD Biosciences flow cytometry instruments by an approved third party, Data Innovations, LLC Technology. Provides a bi-directional connection to the Laboratory Information System (LIS) for transfer of patient information and results.   |   |

## 5.7 Substantial Equivalence

Performance of the BD FACSVia System using the Leucocount Reagent Assay and FACSCComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set and BD Leucocount Reagent is equivalent. These two systems have an intended use with similar operating principles; and both systems were validated using the FACSCalibur flow cytometer. Any differences in technological characteristics are accompanied by information that demonstrates the subject device is as safe and effective as the predicate device. Therefore, the proposed device is substantially equivalent to the predicate, the FACSCComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set and BD Leucocount Reagent.

## 5.8 Performance Data

A summary of the performance data results and study design criteria are provided in **Table 5-4**.

Table 5-4. Performance Summary

| Study                      | Study Design  | Results  |
|----------------------------|---|--|
| Accuracy/Method Comparison | Based on CLSI EP09-A3, <i>Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition</i>             | The BD FACSVia System using the BD Leucocount Reagent Assay demonstrated equivalent performance to the predicate, the FACSCComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set. |
| Precision                  | Based on CLSI EP05-A3, <i>Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Third Edition</i> | Assay dependent. The BD FACSVia System using the BD Leucocount Reagent Assay met the precision acceptance criteria described.  |
| Linearity                  | Based on CLSI EP06-A, <i>Evaluation of the Linearity of Quantitative Measurement Approaches: A Statistical Approach.</i>                  | Assay dependent. The BD FACSVia System using the BD Leucocount Reagent Assay met the linearity acceptance criteria described.  |

| Study             | Study Design  | Results  |
|-------------------|---|--|
| Sample Carryover  | Based on CLSI H44-A2, <i>Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline - Second Edition</i>  | The mean carryover measured from manual acquisition and the mean carryover from Loader acquisition both met the acceptance criteria described.   |
| Reagent Carryover | Low red blood cell and low platelets from BD Leucocount Control samples were stained with calculated dilution of BD Leucocount reagent assay and compared to unstained samples to assess the effect of carryover on BD Leucocount reagent assay results.<br>Carryover Calculation:<br>Reagent Carryover volume per reaction = % volume carryover * 400 ul (reagent volume per reaction) | The mean carryover measured from manual acquisition and the mean carryover from Loader acquisition both met the acceptance criteria described.<br>Reagent carryover is less than the minimum detectable reagent concentration. |

## 5.9 Conclusion

The BD FACSVia System using the Leucocount Reagent Assay demonstrates substantial equivalence to the predicate devices, FACSComp Software and CaliBRITE Beads for use in Flow Cytometer Instrument Set and BD Leucocount Reagent.