DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 16, 2016

BD Biosciences
Attention: Ms. Michelle Sadler
2350 Qume Drive
San Jose, CA 95131-1807

Re: BK150307

Trade/Device Name:	BD FACSVia™ System with BD Leucocount Reagent Assay
Regulation Number:	21 CFR 864.5220
Regulation Name:	Automated Differential Cell Counter
Regulatory Class:	Class II
Product Code:	OYE
Dated:	September 13, 2016
Received:	September 13, 2016

Dear Ms. Sadler:

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. 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.

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 807); labeling (21 CFR 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 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 801), 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" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR 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,

/s/
Basil Golding, MD
Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosures

Indications for Use

510(k) Number: BK150307

Device Name: BD FACSVia™ Flow Cytometer System

Indications For Use:

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.

Indications for Use

510(k) Number: BK150307

Device Name: BD Leucocount™ Kit

Indications For Use:

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.

Indications for Use

510(k) Number: BK150307

Device Name: BD Leucocount™ RBC Control Kit

Indications For Use:

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.

Indications for Use

510(k) Number: BK150307

Device Name: BD Leucocount™ PLT Control Kit

Indications For Use:

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.

Indications for Use

510(k) Number: BK150307

Device Name: BD™ CS&T Beads

Indications For Use:

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.