AUG 2 2013

Section 5: 510(k) Summary

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

The assigned 510(k) number is K131301.

1.0 Submitted By: BD Biosciences
2350 Qume Drive
San Jose, CA 95131 USA

Contact: Kimberly Liedtke
Regulatory Affairs Specialist
Telephone: 408.954.4149
Email: Kimberly_Liedtke@BD.com

Date Prepared: August 1, 2013

2.0 Device Name: BD FACS™ Sample Prep Assistant III
Classification: Class II (21 CFR 864.5220 – Automated Differential Cell Counter)

3.0 Intended Use:
The BD FACS™ Sample Prep Assistant III is intended to prepare human whole blood for flow cytometric analysis on BD FACSCanto™ II and BD FACSCalibur™ flow cytometry systems.

4.0 Indications for Use:

Pipetting blood, reagents, and lysing solution using the following previously cleared assays for flow cytometric analysis on BD FACSCanto II flow cytometry systems:

- BD Multitest 6-Color TBNK Reagent with or without BD Trucount Tubes
- BD Multitest IMK Kit with or without BD Trucount Tubes
- BD Multitest CD3 FITC/CD16+CD56 PE/CD45 PerCP/CD19 APC with or without BD Trucount Tubes
- BD Multitest CD3 FITC/CD8 PE/CD45 PerCP/CD4 APC with or without BD Trucount Tubes

Pipetting blood, reagents, and lysing solution using the following previously cleared assays for flow cytometric analysis on BD FACSCalibur flow cytometry systems:

- BD Multitest IMK Kit with or without BD Trucount Tubes
- BD Multitest CD3 FITC/CD16+CD56 PE/CD45 PerCP/CD19 APC with or without BD Trucount Tubes
- BD Multitest CD3 FITC/CD8 PE/CD45 PerCP/CD4 APC with or without BD Trucount Tubes
- BD Tritest CD3/CD16+56/CD45 with or without BD Trucount Tubes
- BD Tritest CD3/CD19/CD45 with or without BD Trucount Tubes
- BD Tritest CD3/CD4/CD45 with or without BD Trucount Tubes
- BD Tritest CD3/CD8/CD45 with or without Trucount Tubes
- BD Tritest CD4/CD8/CD3 with BD Trucount Tubes

For in vitro diagnostic use.

5.0 Basic Description of the Device:

The BD FACS™ Sample Prep Assistant III (SPA III) is a microprocessor-controlled pipetting and diluting system which automatically prepares whole blood samples using the lyse / no-wash sample preparation method for flow

cytometry. Used as an accessory to the BD FACSCalibur flow cytometer, the SPA III combines fluidic, optic, robotic, and electronic components to automatically prepare samples for acquisition and analysis.

The SPA III pierces the sample tube cap to withdraw sample, aliquots blood and reagent into daughter tubes, and mixes the sample according to preprogrammed or custom protocols. The device also adds lysing solution and automates cleaning procedures. The unit consists of an enclosure, one robotic pipetting module moving in the X/Y/Z axes, a power supply, a central controller unit, fluid pumps, and a barcode reader.

6.0 Predicate Device:

The BD FACSCalibur system, using the BD FACS™ Sample Prep Assistant III (SPA III) is substantially equivalent to the BD FACSCanto II system using the BD FACS™ Sample Prep Assistant III (SPA III). For both systems, the SPA III is used to prepare human whole blood for flow cytometric analysis. When used with the BD FACSCalibur system, the SPA III and manual pipetting are used for the same sample type and result in similar performance characteristics.

7.0 Comparison to the Predicate:

Similarities and Differences:

Characteristic	BD SPA III used with the BD FACSCanto II system (predicate)	BD SPA III used with the BD FACSCanto II and BD FACSCalibur systems (modification)
Intended Use	The BD FACS™ Sample Prep Assistant III is intended to prepare human whole blood for flow cytometric analysis on BD FACSCanto II flow cytometry systems.	The BD FACS™ Sample Prep Assistant III is intended to prepare human whole blood for flow cytometric analysis on BD FACSCanto II and BD FACSCalibur flow cytometry systems.
Sample Type	Whole blood	Same

Preparation Method	Automated	Same
Pipetting Syringe	1 mL sample/reagent syringe 10 mL lyse syringe	Same
Supported primary blood sample tubes	Vacutainer Sarstedt	Same
Probe Rinse	3 pulses of approximately 1 second	Same
Single-dispense excess drawn reagent (waste)	4 µL	Same

8.0 Summary of Performance Data

Study	Study Design	Results
Accuracy	Based on *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline,* CLSI document EP9-A2	The SPA III with the BD FACSCalibur system demonstrated equivalent performance in its ability to prepare human whole blood for flow cytometric analysis.
Precision	Based on *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline,* CLSI document EP5-A2	The SPA III demonstrated system precision within specification.
Carryover	Based on recommendations contained in *Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA*, December 4, 2001	The SPA III demonstrated system carryover within specification.

The BD FACS™ Sample Prep Assistant III with the BD FACSCalibur system demonstrates substantial equivalence to the predicate method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 2, 2013

BD BIOSCIENCES
C/O MS. KIMBERLY LIEDTKE
REGULATORY AFFAIRS SPECIALIST
2350 QUME DRIVE
SAN JOSE, CA 95131

Re: 510(k) Number:	K131301
Trade/Device Name:	BD FACS™ Sample Prep Assistant III
Regulation Number:	21 CFR 862.2750
Regulation Name:	Pipetting and Diluting System for Clinical Use
Regulatory Class:	Class I
Product Code:	PER
Dated:	May 2, 2013
Received:	May 7, 2013

Dear Ms. Liedtke:

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 Part 801); 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), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
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 Statement

510(k) Number (if known): K131301

Device Name: BD FACS™ Sample Prep Assistant III

Intended Use:
The BD FACS™ Sample Prep Assistant III is intended to prepare human whole blood for flow cytometric analysis on BD FACSCanto™ II and BD FACSCalibur™ flow cytometry systems.

Indications for Use:

Pipetting blood, reagents, and lysing solution using the following previously cleared assays for flow cytometric analysis on BD FACSCanto™ II flow cytometry systems:

- BD Multitest 6-Color TBNK Reagent with or without BD Trucount Tubes
- BD Multitest IMK Kit with or without BD Trucount Tubes
- BD Multitest CD3 FITC/CD16+CD56 PE/CD45 PerCP/CD19 APC with or without BD Trucount Tubes
- BD Multitest CD3 FITC/CD8 PE/CD45 PerCP/CD4 APC with or without BD Trucount Tubes

Pipetting blood, reagents, and lysing solution using the following previously cleared assays for flow cytometric analysis on BD FACSCalibur™ flow cytometry systems:

- BD Multitest IMK Kit with or without BD Trucount Tubes
- BD Multitest CD3 FITC/CD16+CD56 PE/CD45 PerCP/CD19 APC with or without BD Trucount Tubes
- BD Multitest CD3 FITC/CD8 PE/CD45 PerCP/CD4 APC with or without BD Trucount Tubes
- BD Tritest CD3/CD16+56/CD45 with or without BD Trucount Tubes
- BD Tritest CD3/CD19/CD45 with or without BD Trucount Tubes
- BD Tritest CD3/CD4/CD45 with or without BD Trucount Tubes
- BD Tritest CD3/CD8/CD45 with or without Trucount Tubes
- BD Tritest CD4/CD8/CD3 with BD Trucount Tubes

For in vitro diagnostic use.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off