510(k) SUMMARY

MAR - 7 2011

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 K102064.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: BD Biosciences
2350 Qume Drive
San Jose, CA 95131 USA

Contact: Marc Glazer
Manager, US Regulatory Affairs
(408) 954-2355
(408) 954-2495 (FAX)

Summary Date: February 25, 2011

Device Name / Classification (21 CFR 807.92(a)(2))

Name: BD FACS™ Sample Prep Assistant III accessory to the BD FACSCanto™ system with BD FACSCanto™ clinical software

Classification: Class II (21 CFR 864.5220) – Automated Differential Cell Counter

Substantially Equivalent/Predicate Device (21 CFR 807.92(a)(3))

The BD FACS Sample Prep Assistant III (SPA III) is substantially equivalent to the BD FACS™ Sample Prep Assistant II (SPA II), both of which are used with the BD FACSCanto system with BD FACSCanto Clinical Software. The SPA III and SPA II are used for the same assay preparation, and result in equivalent performance characteristics.

Device Description (21 CFR 807.92(a)(4))

The BD FACS Sample Prep Assistant 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 FACSCanto 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.

Intended Use (21 CFR 807.92(a)(5))

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.

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

For in vitro diagnostic use.

Technological Characteristics (21 CFR 807.92(a)(6))

The following summary table describes the similarities and differences between the SPA II and SPA III when used with the BD FACSCanto system with BD FACSCanto clinical software.

Table 1: Similarities and Differences

Characteristic	**BD FACS Sample Prep Assistant II** **(predicate)**	**BD FACS Sample Prep Assistant III** **(modification)**
Intended Use	When used as a pre-analytical component of the BD FACSCanto system, the SPA II becomes an accessory to the BD FACSCanto system but does not change the BD FACSCanto system's 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.
Sample Type	Whole blood	Same
Device Classification and Product Code as a Stand-alone Device	Automated Differential Cell Counter 21 CFR 864.5220 Product Code: GKZ Class II	Same
Preparation Method	Automated	Same
Pipetting Syringe	500 µL sample/reagent syringe 2.5 mL lyse syringe	1 mL sample/reagent syringe 10 mL lyse syringe
Supported primary blood sample tubes	Vacutainer	Vacutainer Sarstedt
Probe rinse	One 30 second wash	3 pulses of approximately 1 second
Single-dispense excess drawn reagent (waste)	5 µL	4 µL

The SPA III has modifications over the previous generation. These include reduced sample processing time through the use of larger syringes and reduced wash time; reduced reagent waste; and software upgrades to provide usability enhancements.

Table 2: Performance Data (21 CFR 807.92(b)(1)and (2))

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 FACSCanto system demonstrated equivalent performance.
Precision	Based on *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline*, CLSI document EP5-A2.	The SPA III with the BD FACSCanto system 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 with the BD FACSCanto system demonstrated system carryover within specification.

Conclusions from Performance Data (21 CFR 807.92(b)(3))

The BD FACS Sample Prep Assistant III with the BD FACSCanto system with BD FACSCanto clinical software demonstrates substantial equivalence to the predicate method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

BD Biosciences
c/o Marc Glazer, Ph.D.
Manager, US Regulatory Affairs
2350 Qume Drive
San Jose, CA 95131 USA

MAR 0 7 2011

Re: k102064
Trade/Device Name: BD FACS™ Sample Prep Assistant III
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: February 17, 2011
Received: February 18, 2011

Dear Dr. Glazer:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102064

Device Name: BD FACS™ Sample Prep Assistant III

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

For in vitro diagnostic use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K102064