

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k102064

B. Purpose for Submission:

Modifications to a previously cleared device (BD FACS Sample Prep Assistant II - k050191):

- a. Expanded options for primary sample tubes (in addition to the already available Vacutainer tubes);
- b. Increased throughput by using a shorter wash cycle (three 1-second pulses replace one 30-second wash) and increasing syringe sizes (the sample/reagent syringe is increased to 1 mL from 0.5 mL and the lyse syringe is increased to 10 mL from 2.5 mL)
- c. Reduced reagent waste for single dispenses (4 μ L compared to 5 μ L)
- d. SPA software version 4.0.2 which supports the above hardware changes and adds pre-programmed reagent panels for BD Multitest 6-Color TBNK Reagent (k090967) based on testing results using the Replacement Reagent and Instrument Family Policy (December 11, 2003).

C. Manufacturer and Instrument Name:

BD Biosciences

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

D. Type of Test or Tests Performed:

Specimen processor.

E. System Descriptions:

1. Device Description:

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 with a flow cytometer.

2. Principles of Operation:

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.

3. Modes of Operation:

Automatic, closed mode.

4. Specimen Identification:

To enter the ID, one can scan a primary tube with the barcode scanner, or manually type a unique identification code (Sample ID) into the worklist.

5. Specimen Sampling and Handling:

The carousel rack holds up to 40 uncapped 12 x 75 mm polystyrene secondary tubes and is compatible with the BD FACSTM Loader. Each rack has an identification code stamped on top. A work list can be generated to enter primary tube identification, tube type, position, panel, and secondary tube positions.

6. Calibration:

Not applicable

7. Quality Control:

Quality control is performed in the context of the FACSCanto System.

Manufacturer also recommends verification of accuracy and precision following probe change or replacement.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes X or No _____

F. Regulatory Information:

1. Regulation section:

21 CFR 864.5220 – Automated Differential Cell Counter

2. Classification:

Class II

3. Product code:

GKZ

4. Panel:

81 Hematology

G. Intended Use:

1. Indication(s) for Use:

The BD FACSTM Sample Prep Assistant III is intended to prepare human whole blood for flow cytometric analysis on BD FACSCanto II flow cytometry systems.

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.

2. Special Conditions for Use Statement(s):

None

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

BD FACSCanto system with BD FACSCanto clinical software (k050191)

Note: BD FACS Sample Prep Assistant II is a component of the above mentioned system.

2. Comparison with Predicate Device:

Similarities		
Item	BD FACS Sample Prep Assistant III (k102064)	BD FACS Sample Prep Assistant II (k050191)
Intended Use	The BD FACSTM Sample Prep Assistant III is intended to prepare human whole blood for flow cytometric analysis on BD FACSCanto II flow cytometry systems.	To prepare human whole blood for flow cytometry. 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.
Sample Type	Whole blood	Same
Preparation Method	Automated	Same

Differences		
Item	BD FACS Sample Prep Assistant III (k102064)	BD FACS Sample Prep Assistant II (k050191)
Pipetting Syringe	1 mL sample/reagent syringe 10 mL lyse syringe	500 µL sample/reagent syringe 2.5 mL lyse syringe
Supported primary blood sample tubes	Vacutainer Sarstedt	Vacutainer
Probe rinse	3 pulses of approximately 1 second	One 30 second wash
Single-dispense excess drawn reagent (waste)	4 µL	5 µL

I. Special Control/Guidance Document Referenced (if applicable):

1. CLSI Document. EP5-A2. Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline - Second Edition". 2004.
2. CLSI Document EP9-A2. Method Comparison and Bias Estimation Using Patient Samples; Approved Guidelines - Second Edition. 2002.
3. 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.

J. Performance Characteristics:

1. Analytical Performance:
 - a. Accuracy:
Accuracy was assessed based on Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, CLSI document EP9-A2.

The SPA III was compared to the manual pipetting using the BD Multitest 6-Color TBNK Reagent with BD Trucount Tubes in a 3 site external clinical study. Each site analyzed 255 patient specimens. For CD3+CD4+, CD3+CD8+ and CD3+ (percent and absolute values) mean bias was within ± 1.0 and met the manufacturer's acceptance criteria of 95% CI on bias $\leq 10\%$. For CD3-CD19+ and CD3-CD16+CD56+ (percent and absolute values) mean bias was within $\pm 4.0\%$ and met the manufacturer's acceptance criteria of 95% CI on bias $\leq 20\%$.

The SPA III with the BD FACSCanto system demonstrated equivalent performance.

b. Precision/Reproducibility:

Precision was assessed based on Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline, CLSI document EP5-A2. Pipetting precision was assessed gravimetrically for the BD-defined Multitest protocol using normal donor blood, BD Multi-Check process control, reagent buffer (to represent reagent). The performance for pipetting blood was found to be within the manufacturer's specifications of $50 \mu\text{L} \pm 3\%$ and the performance for pipetting reagent was found to be within the manufacturer's specifications of $20 \mu\text{L} \pm 7\%$.

Precision of the staining and lysing of samples was also assessed. This was demonstrated by measuring the closeness of agreement between independent test/measurement results obtained under stipulated conditions. These conditions include multiple operators (3), multiple instruments (3 SPA III), and duration of testing (21 days) run twice daily in duplicate. The study samples were CD-Chex normal (CDN) and CD-Chex CD4 low (CDL) stained with BD Multitest 6-Color TBNK Reagent in BD Trucount Tubes. Measurements for this study were the absolute counts and percentages of the following lymphocyte subsets: CD3+CD4+, CD3+CD8+, CD3+, CD3-CD19+ and CD3-CD16+CD56+. The manufacturer's acceptance criteria were as follows:

Absolute counts:

95% upper CI on the CV $\leq 10\%$ for CD3+, CD4+ and CD8+

95% upper CI on the CV $\leq 20\%$ for CD19+ and CD16+56+

Percent positives:

95% upper CI on the SD ≤ 2.5

Study results indicate that the device performed according to the manufacturer's acceptance criteria.

c. Linearity:

Not applicable

d. Carryover:

Carryover was assessed 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.

Sample carryover was tested using three donors (in duplicate) on three SPA III instruments. These studies indicated that the device performed within the

manufacturer's specification of <0.2%.

Reagent carryover was tested using three donors (in duplicate) on three SPA III instruments. These studies indicated that the device performed with a carry over that was within the manufacturer's specification of <0.01%. The SPA III with the BD FACSCanto system demonstrated system carryover within specification.

e. Interfering Substances:

Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

Not applicable

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.