

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

K041074

B. Purpose for Submission:

New device

C. Manufacturer and Instrument Name:

Becton Dickinson Immunocytometry Systems

BD FACS Canto Flow Cytometer with BD FACS Canto Software

D. Type of Test or Tests performed:

Semi-quantitative, optical

E. System Descriptions:

1. Device Description:

The BD FACS Canto System is comprised of a flow cytometer, a wet cart, and a computer. The wet cart contains operational fluids, the flow cytometer acquires and analyzes the sample, and the computer displays and prints the analysis. The flow cytometer utilizes three subsystems: fluidics, optics and electronics. It contains two software packages, one for manual immunophenotyping and one for automatic immunophenotyping, and is compatible with the BD FACS Loader for automatic sample introduction.

2. Principles of Operation:

The BD FACS Canto flow cytometer combines fluidic, optic, and electronic subsystems to measure and analyze signals emitted when particles flow in a liquid stream through a glass cuvette, at which beams of laser light are directed. The emitted light from these particles provides information about cell size, shape, granularity, and fluorescence intensity.

3. Modes of Operation:

Random access or automatic sampling, open tube

4. Specimen Identification:

Manual identification by operator or instrument automatic numbering

5. Specimen Sampling and Handling:

Lysed no-wash cell suspension prepared from whole blood sample; open tube using manual or automated sample introduction.

6. Calibration:

Not provided.

7. Quality Control:

Instrument quality control is performed to ensure consistent instrument performance. Quality control parameters should be as constant as possible using the same particle (beads) type, lot number and flow rate from day to day. When using BD FACS Canto software, a process control is added to a worklist, entered as "Control" in the sample name, and run as a typical sample. The control results are automatically exported to a spreadsheet file and the file is used to track results over time.

8. Software:
BD FACS Canto software combines instrument QC and setup, acquisition and analysis, and optional automated sample loading. Compensation settings are recalculated automatically during voltage adjustment. Auto-gating algorithms isolate populations of interest, but the software allows manual gating, if necessary. Internal quality control checks the validity of the results. The results are reported in percentage and absolute counts.

FDA has reviewed the applicant's Hazard Analysis and software Documentation: 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, Counter, differential cell
4. Panel:
Hematology (81)

G. Intended Use:

1. Indication(s) for Use:
BD FACS Canto Flow Cytometer with BD FACS Canto Software is used for immunophenotyping in clinical laboratories, using previously cleared IVD assays for flow cytometry that utilize the lyse no-wash sample preparation method. The lymphocytes subsets include; CD3⁺CD8⁺, CD3⁺CD4⁺, CD3⁻CD16⁺ and/or CD56⁺, CD3⁻CD19⁺, and CD3⁺.
2. Special Condition for use Statement(s):
Not applicable.

H. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) numbers:
BD FACSCalibur, K973483
2. Comparison with Predicate Device:

Item	Device	Predicate
	<i>BD FACS Canto Flow Cytometer with BD FACS Canto Software</i>	<i>BD FACSCalibur with FACSComp Software</i>
Intended Use	For use as an <i>in-vitro</i> diagnostic device for identification and enumeration of lymphocyte subsets in human cells in suspension using a lyse no-wash sample preparation method for flow cytometry.	Same
Lasers	Blue – 488 nm solid state Red – 633 nm HeNe	Blue – 488 nm argon ion Red – 635 nm diode laser
Software	BD FACS Canto	BD Multiset™

Differences		
Item	Device	Predicate
Detectors	1 FSC photodiode 1 SSC photomultiplier tube 4 fluorescence detector PMTs plus 2 additional fluorescence detector PMTs	Same FSC Same SSC 4 fluorescence detector PMTs
Optics	Laser light delivered by fiber optics, prisms and lasers Emitted light delivered by collection an fiber optics	Laser light delivered by mirrors, prisms and lenses Emitted light delivered by mirrors
Electronics	Digital	Analog
Fluidics	Addition of an external wet cart to supply bulk fluids and hold waste.	BD FACS Flow sheath fluid cubitainer

I. Standard/Guidance Document Referenced (if applicable):

EP9-A2 *Method Comparison and Bias Estimation Using Patient Samples*,
Approved Standard-Second Edition, NCCLS

EP5A *Evaluation of Precision Performance of Clinical Chemistry Device Approved Guideline*, NCCLS

Class II Special Controls Guidance Document: Premarket Notification for Automated Differential Cell Counters for immature or Abnormal Blood Cells; Final Guidance for Industry and FDA.

EP6-A *Evaluation of the Linearity of Quantitative Measurement Procedures*,
Approved Guideline, NCCLS

ICSH Expert Panel on Cytometry, Guidelines for Evaluation of Blood Analyzers,
Cytometry Clinical Laboratory Hematology, 1994, 16, 157

J. Performance Characteristics:

1. Analytical Performance:

a. *Accuracy:*

A comparison study was performed using 108 samples from both normal and abnormal donors from two donor sites. The reported subset percentages and absolute counts were compared to the predicate device. See linear regression results below:

Subset percentage

Measurement	Unit	CD3	CD4	CD8	CD19	CD16+56
Number		108	108	108	108	108
Slope		1.00	0.99	1.00	0.99	1.0
Confidence Interval		0.98,1.02	0.98,1.00	0.98,1.02	0.97,1.02	0.97, 1.02
Intercept	%	-0.17	0.26	0.27	-0.05	0.39
Confidence Interval		-1.86, 1.52	-0.06, 0.57	-0.62, 1.16	-0.41,0.31	0.01,0.78
Correlation Coefficient		0.993	0.998	0.996	0.994	0.989

Subset absolute counts

Measurement	Unit	CD3	CD4	CD8	CD19	CD16+56
Number		108	108	108	108	108
Slope		0.99	0.97	0.96	1.02	0.95
Confidence Interval		0.96,1.02	0.97,0.99	0.93,1.00	1.00,1.05	0.92, 0.99
Intercept	Cells/ μ L	-6.27	10.8	24.6	-7.93	10.8
Confidence Interval		-53.2,40.7	-5.51,27.0	-8.84,58.1	-17.9,2.01	1.87,19.8
Correlation Coefficient		0.987	0.991	0.983	0.990	0.981

b. Precision/Reproducibility:

Two levels of control cells were run on three BD FACS Canto instruments equipped with a BD FACS Loader by three different operators. Measurements were obtained from two separate runs per day over 20 days; each runs was separated by a minimum of four hours. BD FACS Canto Flow Cytometer with BD FACS Canto Software demonstrated acceptable within run and total precision according to the precision criteria for each subset listed below:

Lymphocyte subset	Within-Run Precision Criteria (%)		Total Precision Criteria (%)	
	%	Absolute count	%	Absolute count
CD3	<2.5	<10	<2.5	<10
CD4	<2.5	<10	<2.5	<10
CD8	<2.5	<10	<2.5	<10
CD19	<2.5	<15	<2.5	<15
CD16+56	<2.5	<20	<2.5	<20

c. Linearity:

Linearity was tested using data for each lymphocyte subset collected from 21 samples; seven dilutions with three replicate each (using the BD Multitest IMK Kit). See absolute count results below:

Lymphocyte subset	Linearity Range (cells/ μ L)	R ² (%)
CD3	48-9627	99.98
CD4	29-5827	99.96
CD8	22-4076	99.95
CD19	5-1131	99.93
CD16+56	4-671	99.78

- d. *Carryover:*
Not performed. Carryover studies presented for BD FACS Canto with BD FACS Diva software (K040725) provided acceptable results. BD FACS Canto software introduced no hardware changes or mechanical modifications to affect carryover.
- e. *Interfering Substances:*
Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above

K. Conclusion:

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