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

A. 510(k) Number:
K040725

B. Purpose for Submission:
New device

C. Manufacturer and Instrument Name:
Becton Dickinson Immunocytometry Systems
BD FACS Canto Flow Cytometer with BD FACS Diva 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 one software package for manual 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 washed cell suspension 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. The BD FACS Diva software provides a template to use as a starting point for the QC experiment. The QC experiment contains a preformatted global worksheet. The worksheet contains the analysis objects (plots, gates, statistics) needed to perform QC.

8. Software:
   BD FACSDiva software can be used to facilitate instrument setup, communicate between the cytometer and the computer, and acquire and analyze data. The software allows the setting of gates for multicolor data analysis, and to report lymphocyte subset percentage.

   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 Diva Software is used for immunophenotyping in clinical laboratories, using previously cleared IVD assays for flow cytometry that utilize the lyse 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
	BD FACS Canto Flow Cytometer with FACS Diva Software	***BD FACSCalibur with FACSComp Software***
Intended Use	For use as an ***in-vitro*** diagnostic device for identification and enumeration of lymphocyte subsets in human cells in suspension using a lyse 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 FACSDiva version 4.0	BD Simulset™
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 Haematolog*, 1994, 16, 157-

J. Performance Characteristics:

1. Analytical Performance:
   - *a. Accuracy:*

     A comparison study was performed using 128 samples from both normal and abnormal donors from three donor sites. The reported

subset percentages were compared to the predicate device. See linear regression results below:

Measurement	Unit	CD3	CD4	CD8	CD19	CD16+56
Number		128	128	128	128	128
Slope		0.99	1.03	0.98	1.01	0.96
Confidence Interval		0.96,1.02	1.01,1.05	0.96,1.00	0.97,1.06	0.93,0.98
Intercept	%	1.9	-0.50	-99	-0.20	-0.85
Confidence Interval		-0.31, 4.11	-0.03, 0.02	-2.07,0.09	-0.83,0.44	-1.28,0.41
Correlation Coefficient	%	0.986	0.995	0.993	0.968	0.988

b. Precision/Reproducibility:

Two levels of control cells were run on three BD FACS Canto instruments equipped with a BD FACS Loader by four different operators. Measurements were obtained from two separate runs per day over 20 days; each runs separated by a minimum of four hours.

Precision Summary

Lymphocyte subset	Within-Run Precision (SD)	Within-Run CV	Total Precision (SD)	Total CV
Unit	%	%	%	%
CD3	1.04	1.6	1.17	1.8
CD4	0.92	2.8	0.99	3.0
CD8	1.06	3.5	1.15	3.8
CD19	0.82	4.9	0.89	5.3
CD16+56	0.79	4.8	0.83	5.1

c. Linearity:

Linearity was tested using beads with different fluorescence intensities. Five to seven intensities were tested for each of the six detectors. Ten replications were measured on each of three instruments. A summary of the results are as follows:

Detector	Reference intensity range	Conclusion
FITC (FL1)	600-330,000 MEFL	Acceptable
PE (FL2)	400-300,000 MEPE	Acceptable
PerCP-Cy5.5 (FL3)	1,900-1,115,000 MEPCY5	Acceptable
APC (FL4)	0.025-100 RFI	Acceptable
PE-Cy7 (FL5)	0.098-100 RFI	Acceptable
APC-Cy7 (FL6)	0.025-100 RFI	Acceptable

d. Carryover:

A carryover study was performed. Percent carryover was estimated by introducing three consecutive abnormally high leucocyte prepared

samples followed by three consecutive abnormally low leucocyte prepared samples, and calculating the percent difference. All data collected with and without the BD FACS Loader met acceptable criteria.

e. Interfering Substances:
Not provided

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.