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

A. 510(k) Number:
K040026

B. Purpose for Submission:
New device

C. Analyte:
$CD3^+CD8^+$, $CD3^+CD4^+$, $CD3^-CD16^+$ and/or $CD56^+$, $CD3^-CD19^+$, and $CD3^+$.

D. Type of Test:
Semi-quantitative, optical

E. Applicant:
Becton Dickinson Immunocytometry Systems

F. Proprietary and Established Names:
BD FACS™ 7-Color Setup Beads

G. 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)

H. Intended Use:
1. Intended use(s):
   BD FACS 7-color setup beads are for in-vitro use on the BD FACSCanto flow cytometer with BD FACSCanto software. The beads are used to adjust detector voltages, to set fluorescence compensation, and to monitor daily instrument performance.
2. Indication(s) for use:
   BD FACS 7-color setup beads are for in-vitro use on the BD FACSCanto flow cytometer with BD FACSCanto software. The beads are used to adjust detector voltages, to set fluorescence compensation, and to monitor daily instrument performance.
3. Special condition for use statement(s):
   For use on the BD FACSCanto flow cytometer with BD FACSCanto software.
4. Special instrument Requirements:
   Not Applicable.

I. Device Description:
BD FACS 7-color setup beads are supplied as a kit containing 25 individually packaged setup bead tubes, a bottle of bead diluent, target values, and spectral overlap factors. The beads are used to set up a flow cytometry before running

immunophenotyping assays on stained cells. Each setup bead tube contains a lyophilized pellet that is rehydrated with bead diluent. Each pellet contains a mixture of 4um and 6-um beads that are either unlabeled or individually labeled with fluorophores; fluorescein, R-phycoerythrin (PE), Peridinin chlorophyll protein (PerCP), allophycocyanin (APC), PerCP cyanine 5.5 tandem (PerCP-Cy5.5), PE cyanine 7 tandem (PE-Cy7), APC cyanine 7 tandem (APC-Cy7).

J. Substantial Equivalence Information:
    1. Predicate device name(s):
        BD CaliBRITE Beads
    2. Predicate K number(s):
        K973483
    3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
	BD FACS 7-color Setup Beads	*BD CaliBRITE Beads*
Intended Use	To adjust detector voltages, to set fluorescence compensation, and to monitor daily instrument performance.	Same
Storage	2-8° C, 7 months	Same
Fluorophores		
R-phycoerythrin (PE)	Same	Same
Peridinin Chlorophyll protein (PerCP-Cy5.5)	Same	Same
PerCP cyanine 5.5 tandem (PerCP-Cyb5.5)	Same	Same
Allophycocyanin (ACP)	Same	Same
Differences		
Item	**Device**	**Predicate**
Form	Lyophilized	Liquid
Fluorophores		
Fluorescein.	Fluorescein isothiocyanate (FITC) derivative used for starting material for conjugation resulting in fluorescein surface-coupled	Fluorescein EX derivative used as starting material for conjugation resulting in fluorescein surface-coupled PMMA beads.

	PMMA beads.	
PE-Cy7	PE cyanine 7 tandem (PE-Cy7) same as predicate with the exception that PE is derivatized with cyanine7	NA
APC-Cy7	APC cyanine 7 tandem (APC-Cy7); same as predicate with the exception that APC is derivatized with cyanine 7	NA

K. Standard/Guidance Document Referenced (if applicable):
Not Applicable

L. Test Principle:
The dual laser FACS-brand flow cytometer is set up for data acquisition and analysis each day using BD FACS 7-color setup beads and BD flow cytometry system software to adjust the forward scatter (FSC) photodiode, the photomultiplier tube (PMT) voltages for side scatter (SSC) and the fluorescence detectors.

M. Performance Characteristics (if/when applicable):
    1. Analytical performance:
        a. Precision/Reproducibility:
        MFI Specification: The study was set up so that all tubes were hydrated at different times with BD FACS setup bead diluent, incubated at 2-8C, an then all read together on the flow cytometer after the last time point. Each time point is the average of 6 acquisitions-3 acquisitions of each of the two duplicate bead tubes. Results: All beads were stable and within specification.

        Spectral Overlap: Spectral overlap was calculated from the same Data set which determined little or no change and within specification

        b. Linearity/assay reportable range:
        Not applicable
        c. Traceability (controls, calibrators, or method):
        Not applicable
        d. Detection limit:
        Not applicable
        e. Analytical specificity:
        Not applicable
        f. Assay cut-off:
        Not applicable
    2. Comparison studies:
        a. Method comparison with predicate device:
        Not applicable
        b. Matrix comparison:

Not applicable
3. Clinical studies:
    a. *Clinical sensitivity:*
       Not applicable
    b. *Clinical specificity:*
       Not applicable
    c. *Other clinical supportive data (when a and b are not applicable):*

4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   Not applicable

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