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Traditional 510(k) Summary

A. Applicant

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B. Contact Person

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C. Trade name: ADAMII CD34 System

Classification name: Automated Differential Cell Counter

Classification: 21 CFR §864.5220, Product code GKZ, Class II

- Secondary Classification

Classification name: Flow Cytometric Reagents and Accessories

Classification: 21 CFR §864.5220, Product code OYE, Class II

D. Predicate device: BD Stem Cell Enumeration Kit (BK210652) for use on BD flow cytometers (FACS Lyrics)

E. Indications for Use:

ADAMII CD34 System includes ADAMII-CD34 Kit which is designed for use with ADAMII (Instrument), a benchtop image-based fluorescence cell counter. ADAMII CD34 System provides enumeration of viable CD34+ cells, viable CD45+ cells, and calculates percentage of viable CD34+ cells out of viable CD45+ cells. ADAMII CD34 System can be used for mobilized peripheral blood (MPB) collected in Na-Heparin or EDTA, fresh and thawed hematopoietic progenitor cell – apheresis (HPC-A) collected in ACD or ACD+Heparin, fresh cord blood (FCB) collected in CPD, and thawed frozen cord blood (TFCB) collected in CPD and stored with 10% DMSO, 1% Dextran 40.

ADAMII CD34 System is intended for use in clinical laboratories and for in vitro diagnostic use only. It is not intended for use in point-of-care settings.

Device Description

ADAMII-CD34 Kit utilizes fluorescence-labeled antibodies and nucleic acid staining dye to quantify absolute counts (cells/µL) of viable CD34+ hematopoietic cells and the percentage of viable CD34+ out of viable CD45+ cells. The purpose of this 510(k) is to add new sample types to BK231031; thawed HPC-A.

ADAMII-CD34 Kit includes the following components:

- ADAMII CD34 Reagent
- ADAMII Calibration bead
- ADAMII 10X RBC Lysis Buffer
- ADAMII Assay slides

ADAMII (Instrument) is an image-based fluorescence cell counter supplied with a laptop pre-installed with ADAMII-CD34 software. ADAMII (Instrument) is a 4-channel (Bright field, PE, FITC and PerCP) bench-top imaging platform equipped with state-of the-art optics and a slide holder that accepts ADAMII Assay Slide. ADAMII (Instrument) is based on quantitative fluorometric assay technology capable of quantifying single or multiple fluorophore(s) by measuring LED-induced fluorescence from stained cells. ADAMII Software controls graphical user interface, communication with hardware, database management and data analysis. The software also controls the mechanical components including motors, light sources, and acquisition of images from CCD camera. After completion of image acquisition, ADAMII Software displays and saves results. Final results include (1) Viable CD34+ cells [/µL], (2) Viable CD45+ cells [/µL], (3) Total CD34+ cells [/µL], (4) Total CD45+ cells [/µL], (5) CD34 Viability [%], (6) CD45 Viability [%], (7) the ratio of Viable CD34+ out of Viable CD45 [%].

F. Substantial Equivalence Discussion

An overview of the similarities and differences between the ADAMII-CD34 Kit and the predicate is provided in the Tables 1 – 3 below.

Table 1 General

	Subject Device ADAMII CD34 System	Predicate Device BD Stem Enumeration Kit BK210652
Indications for Use	ADAMII CD34 System includes ADAMII-CD34 Kit which is designed for use with ADAMII (Instrument), a benchtop image-based fluorescence cell counter. ADAMII CD34 System provides enumeration of viable CD34+ cells, viable CD45+ cells, and calculates percentage of viable CD34+ cells out of viable CD45+ cells. ADAMII CD34 System can be used for mobilized peripheral blood (MPB) collected in Na-Heparin or EDTA, fresh and thawed hematopoietic progenitor cell – apheresis (HPC-A) collected in ACD or ACD+Heparin, fresh cord blood (FCB) collected in CPD, and thawed frozen cord blood (TFCB) collected in CPD and stored with 10% DMSO, 1% Dextran 40. ADAMII CD34 System is intended for use in clinical laboratories and for in vitro diagnostic use only. It is not intended for use in point-of-care settings.	The BD® Stem Cell Enumeration Kit is intended for enumeration of viable dual positive CD45+/CD34+ hematopoietic stem cell populations to determine absolute counts (cells/µL) of viable CD34+ and the percentages of viable CD45+/CD34+ hematopoietic stem cells (%CD34). The following cellular-based products (specimens) can be analyzed with this kit: •Normal and mobilized peripheral blood •Fresh and thawed leukapheresis products •Fresh and thawed bone marrow •Fresh and thawed cord blood The kit is intended for in vitro diagnostic (IVD) use on any of the following flow cytometer systems: •BD FACSLyric™ flow cytometer using BD FACSuite™ Clinical application •BD FACSCanto™ II flow cytometer using BD FACSCanto™ clinical software •BD FACSCalibur™ flow cytometer using BD CellQuest™ or BD •CellQuest™ Pro software
Principle Method/Technology	This assay is performed by staining the sample with the reagent and loaded into an individual ADAMII assay slide for absolute counts. When a sample is mixed with reagent, the fluorochrome labeled antibodies and nucleic acid dyes bind specifically to the cell surface and dead cell nucleic acids. Lysis buffer is added to lyse erythrocytes before the sample is loaded into an assay slide. The slide is placed on the precision stage of ADAMII (Instrument), an image-based fluorescence cell counter. After acquiring images and analyzing them, the concentrations of viable CD34+ cells and viable CD45+ cells, and the percentage of viable CD34+ cells in viable CD45+ cell population are calculated.	The single-tube assay is performed by staining the sample with the reagent in individual BD Trucount™ tubes for absolute counts. When a sample is added to the reagent, the fluorochrome-labeled antibodies in the reagent bind specifically to the cell surface. Additionally, the lyophilized pellet in the BD Trucount™ tubes dissolves, releasing a known number of fluorescent beads. The dye 7-AAD is added to assess viability of the cells. Cells that are 7-AAD+ are not viable. Ammonium chloride is added to lyse erythrocytes before the sample is acquired on a flow cytometer. During analysis of the sample, the concentration of viable CD34+ cells and viable CD45+ cells, and the percentage of viable CD34+ cells in the viable CD45+ cell population, are calculated.

Table 2 Reagent Kits and Sample

	Subject Device ADAMII-CD34 Kit	Predicate Device BD Stem Cell Enumeration Kit
Sample type/anticoagulants	• Mobilized peripheral blood (MPB) collected in Na-Heparin or EDTA • Fresh and thawed Hematopoietic progenitor cell – apheresis (HPC-A) collected in ACD or ACD+Heparin • Fresh cord blood collected in CPD • Thawed frozen cord blood collected in CPD and stored with 10% DMSO and 1% Dextran 40.	• Normal and mobilized peripheral blood collected with either EDTA, ACD-A, heparin, or CPD anticoagulants • Fresh and thawed leukapheresis products collected with a mixture or single source of EDTA, ACD-A, or heparin anticoagulants • Fresh and thawed bone marrow collected with either EDTA, ACD-A, or heparin anticoagulants • Fresh and thawed cord blood collected with either EDTA, ACD-A, heparin, or CPD anticoagulants
Parameters in: ADAMII Indications for Use/ BD Principle/Methods	Viable CD34 cells/µL Percentage of viable CD34 of viable CD45 Viable CD45 cells/µL	Viable CD34 cells/µL Percentage of viable CD34 of viable CD45 Viable CD45 cells/µL
Other parameters measured and outputted[1]	Total CD34 cells/µL CD34 viability % Total CD45 cells/µL CD45 viability %	Total CD34 cells/µL CD34 viability % Total CD45 cells/µL CD45 viability %
Kit components	CD34-PE/CD45-PerCP/Sytox Blue reagent Calibration bead solution Ammonium chloride lysing solution ADAMII Assay Slides	• CD45 FITC/CD34 PE reagent • 7-aminoactinomycin-D (7-AAD) reagent • Ammonium chloride lysing solution • BD Trucount tubes
Measuring range	CD34+ cells: 1 – 1,000 cells/µL	For FACSLyric flow cytometer: CD34+ cells: 1 – 1,000 cells/µL For FACSCalibur flow cytometer: CD34+ cells: 0 – 1,000 cells/µL
Measuring time	~ 7 min/test	
Sample volume	MPB or HPC-A : 20 µL Cord blood : 50 µL	100 µL
Measuring volume	~ 8 µL	Not reported

Sample stability	• MPB: Stain specimens within 24 hours of collection • Fresh HPC-A Products: Stain specimens within 24 hours of collection • Thawed HPC-A Products: Stain immediately after thawing • Fresh Cord Blood: Stain specimens within 48 hours of collection • Thawed Frozen Cord Blood: Stain immediately after thawing	• Normal Peripheral Blood: Stain specimens within 24 hours of collection • Mobilized Peripheral Blood: Stain specimens within 24 hours of collection • Fresh Leukapheresis Products: Stain specimens within 24 hours of collection • Fresh Cord Blood: Stain specimens within 48 hours of collection • Fresh Bone Marrow: Stain specimens within 24 hours of collection • Thawed Leukapheresis Products: Stain immediately after thawing • Thawed Cord Blood: Stain immediately after thawing • Thawed Bone Marrow: Stain immediately after thawing
Stain sample stability	• MPB: Keep prepared samples on wet ice and measure within 1 hour of lysing • Fresh HPC-A: Keep prepared samples on wet ice and measure within 1 hour of lysing • Thawed HPC-A: Measure immediately post-lysis • Fresh Cord Blood: Keep prepared samples on wet ice and measure within 1 hour of lysing • Thawed Frozen Cord Blood: Measure immediately post-lysis	• Fresh Leukapheresis Products: Acquire within 1 hour of lysing • Mobilized Peripheral Blood: Acquire within 1 hour of lysing • Fresh Cord Blood: Acquire within 1 hour of lysing • Thawed Cord Blood: Acquire immediately post-lysis
Interfering conditions	No interference was observed in samples with up to 7.5mg/mL of albumin. No interference was observed in samples with up to 10mg/dL of bilirubin. No interference was observed in samples with up to 550µg/mL of cyclophosphamide. No interference was observed in samples with up to 50mg/dL of hemoglobin. No interference was observed in samples with up to 0.25µg/mL of doxorubicin. No interference was observed in samples with up to 60ng/mL of G-CSF. No interference was observed in samples with up to 250mg/dL of intralipid. No interference was observed in samples with up to 20µg/mL of paclitaxel. No interference was observed in samples with up to 1% of gamma globulin.	No interference was observed in samples with up to 60g/dL of albumin. No interference was observed in samples with up to 40mg/dL of bilirubin. No interference was observed in samples with up to 55mg/dL of cyclophosphamide. No interference was observed in samples with up to 1g/dL of hemoglobin. No interference was observed in samples with up to 1.932µg/mL of doxorubicin. No interference was observed in samples with up to 60ng/mL of G-CSF. No interference was observed in samples with up to 1,140mg/dL of intralipid. No interference was observed in samples with up to 10.8µg/mL of paclitaxel.

Table 3 Instruments

	ADAMII	BD FACSLyric™
Light Source	Green LED (525nm) Blue LED (488nm)	Blue laser: 488 nm, 20 mw Red laser: 640 nm, 40 mw Violet laser: 405 nm, 40 mw
Fluorescence filters	FITC Ex 466/40, Em 525/50 PE Ex 510/42, Em 572/28 PerCP Ex 525/50, Em 650LP	FITC 527/32 PE 586/42 PerCP 700/54 PE-Cy7 783/56 APC 660/10 APC-Cy7 783/56
Method of Detection	High-sensitivity monochrome CCD	Photodiode and PMT
Objective Lens	10X objective and 0.7X tube lens	Flow cell lens: 1.2 NA
Stage	Automated X-Y-Z stage	Manual, Automated universal loader (optional)
Exported formats: Image	JPEG	N/A
Electronic input	12V DC, 5.0A	2 A, 200 W
Operating Power	100 – 240 VAC, 1.5 A 50/60 Hz	100 – 240 V ± 10% VAC 50 – 60 ± 10% Hz
Operating environment	5 – 40°C, 20 -95%	15 - 30°C, 15 – 85%
Weight	19.3 kg	~ 70 kg
Dimensions	30W x 42D x 37H cm	107W x 58D x 58H cm

G. Summary of Performance Data:

1. Summary of Method Comparison/Accuracy

ADAMII-CD34 Kit compared to BD Stem Cell Enumeration Kit **Pooled Data**			
Parameters	N	Relative Difference to Predicate (%)	
		Mean Relative Bias	95% CI
viable CD34+ cell counts [cells/µL]	1089	1.14%	0.44% to 1.84%
ratio of viable CD34 out of viable CD45 [%]	1089	1.37%	0.57% to 2.16%
viable CD45+ cell count [1,000 cells/µL]	1089	-0.17%	-0.70% to 0.37%

ADAMII-CD34 Kit Regression Analysis				
Parameter	N	R^2	Slope (95% CI)	Intercept (95% CI)
Pooled data				
CD34 (cells/µL)	1089	0.99	1.00 (1.00-1.01)	0.05 (-0.2-0.36)
%CD34 in CD45	1089	0.98	1.02 (1.01-1.03)	0.00 (0.00-0.00)
CD45 (1000 cells/µL)	1089	0.99	0.99 (0.98-0.99)	0.18 (0.10-0.28)
Thawed HPC-A				
CD34 (cells/µL)	176	0.98	1.00 (0.98-1.01)	3.88 (-0.75-9.15)
% CD34 in CD45	176	0.95	1.03 (0.99-1.07)	0.01 (-0.01-0.03)
CD45 (1000 cells/ µL)	176	0.98	0.94 (0.91-0.98)	1.16 (-0.03-2.50)

2. Summary of Precision

			Clinical samples, CV [%]		
			Site1	Site2	Site3
Thawed HPC-A	Viable CD34 counts	Low	9.65	8.76	10.22
		Mid1	10.46	7.61	9.65
		Mid2	7.25	5.26	9.31
		High	7.15	5.46	9.11
	Viable CD34 %	Low	9.66	6.45	7.75
		Mid1	8.50	9.34	8.06
		Mid2	8.40	7.44	6.78
		High	6.60	6.04	6.82

3. Summary of Linearity

- We have established following linearities.
    - CD34
        - MPB: 1 ~ 100 cells/µL
        - HPC-A: 1 ~ 1,000 cells/µL
        - Cord blood: 1 ~ 120 cells/µL

4. Summary of Sample Stability
   For thawed HPC-A samples, the age of stored sample and the age of stained sample are immediately after thawing and lysing, respectively.

5. Summary of Analytical Sensitivity
   For thawed HPC-A samples, a LoB of 1.38 cells/µL, LoD of 8.15 cells/µL, and LoQ of 40.06 CD34 cells/µL for viable CD34 counts were established.

H. Proposed Labeling

The labeling complies with 21 CFR §809.10. Symbols used in labeling comply with ISO 15223- 1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

I. Compliance with standards and guidelines

Testing complied with the following guidelines except where modifications were required by FDA:

- EN 61010-1:2010 (ed 3) Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
- EN 61010-2-081:2001 (ed 1) +A1:2003 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
- EN 61010-2-101:2002 (ed 1) Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements
- EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
- CLSI EP05-A3, Evaluation of Precision Performance of Quantitative Measurement Methods
- CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline
- CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guidelines

- CLSI EP09-A3, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (*withdrawn but current at time of testing*)

J. Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence determination when compared to the predicate device.